ConforMIS Inc
Form 10-Q
November 09, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

OR

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

For the transition period from to

Commission file number: 001-37474

ConforMIS, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**56-2463152**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
28 Crosby Drive **Bedford, MA**	**01730**
(Address of principal executive offices)	(Zip Code)

(781) 345-9001

(Registrant s telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o

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

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

As of October 30, 2015 there were 40,712,347 shares of Common Stock, $0.00001 par value per share, outstanding.

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ConforMIS, Inc.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(in thousands, except share and per share data)

	September 30, 2015 (unaudited)	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	$ 139,202	$ 37,900
Accounts receivable, net	8,260	9,119
Inventories	10,664	7,691
Prepaid expenses and other current assets	2,124	1,158
Total current assets	160,250	55,868
Property and equipment, net	10,655	8,696
Other Assets		
Restricted cash	720	4,438
Intangible assets, net	1,057	1,243
Goodwill	753	753
Other long-term assets	283	280
Total assets	$ 173,718	$ 71,278
Liabilities and stockholder s equity		
Current liabilities		
Accounts payable	$ 5,849	$ 3,618
Accrued expenses	6,953	6,942
Deferred revenue	305	
Current portion of long-term debt	289	272
Total current liabilities	13,396	10,832
Other long-term liabilities	240	271
Deferred revenue	4,701	
Long-term debt	258	10,348
Total liabilities	18,595	21,451
Commitments and contingencies		
Stockholders equity		
Convertible preferred stock, $0.00001 par value:		
Authorized: Zero and 53,496,241 shares authorized at September 30, 2015 and December 31, 2014, respectively, zero and 50,985,652 shares issued and outstanding September 30, 2015 and December 31, 2014, respectively; (aggregate liquidation value of $0 and $352,626 at September 30, 2015 and December 31, 2014, respectively)		

Preferred stock, $0.00001 par value:				
Authorized: 5,000,000 and zero shares authorized at September 30, 2015 and December 31, 2014, respectively; no shares issued and outstanding as of September 30, 2015 and December 31, 2014				
Common stock, $0.00001 par value:				
Authorized: 200,000,000 and 80,000,000 shares authorized at September 30, 2015 and December 31, 2014, respectively; 40,709,155 and 4,286,164 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively				
Additional paid-in capital		465,818		318,420
Accumulated deficit		(310,352)		(268,096)
Accumulated other comprehensive loss		(343)		(497)
Total stockholders equity		155,123		49,827
Total liabilities and stockholders equity	$	173,718	$	71,278

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

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CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue				
Product	$ 13,490	$ 12,002	$ 43,953	$ 33,975
Royalty	404		3,863	
Total revenue	13,894	12,002	47,816	33,975
Cost of revenue	10,340	7,351	30,392	21,961
Gross profit	3,554	4,651	17,424	12,014
Operating expenses				
Sales and marketing	10,225	7,083	29,563	22,541
Research and development	3,885	3,969	12,218	11,163
General and administrative	5,656	3,927	16,790	11,775
Total operating expenses	19,766	14,979	58,571	45,479
Loss from operations	(16,212)	(10,328)	(41,147)	(33,465)
Other income and expenses				
Interest income	24	30	92	80
Interest expense	(911)	(89)	(1,380)	(178)
Other income (expense)			208	
Total other expenses	(887)	(59)	(1,080)	(98)
Loss before income taxes	(17,099)	(10,387)	(42,227)	(33,563)
Income tax provision	8	9	29	29
Net loss	$ (17,107)	$ (10,396)	$ (42,256)	$ (33,592)
Net loss per share - basic and diluted	$ (0.45)	$ (2.44)	$ (2.69)	$ (7.95)
Weighted average common shares outstanding - basic and diluted	37,933,069	4,267,148	15,688,686	4,224,454

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

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CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss

(unaudited)

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	$ (17,107)	$ (10,396)	$ (42,256)	$ (33,592)
Other comprehensive income (loss)				
Foreign currency translation adjustments	(60)	(377)	154	(543)
Comprehensive loss	$ (17,167)	$ (10,773)	$ (42,102)	$ (34,135)

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

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CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2015	**2014**
Cash flows from operating activities		
Net loss	$ (42,256)	$ (33,592)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization expense	1,891	1,545
Amortization of debt discount	135	18
Stock-based compensation expense	2,594	1,796
Provision for bad debts on trade receivables	171	(37)
Disposal of long term assets	2	
Changes in operating assets and liabilities:		
Accounts receivable	687	(1,573)
Inventories	(2,974)	(73)
Prepaid expenses and other assets	(969)	(394)
Accounts payable and accrued liabilities	2,242	281
Deferred royalty revenue	5,009	
Other long-term liabilities	(31)	(197)
Net cash used in operating activities	(33,499)	(32,226)
Cash flows from investing activities:		
Acquisition of property and equipment	(3,666)	(849)
Decrease (increase) in restricted cash	3,717	768
Net cash (used) provided by investing activities	51	(81)
Cash flows from financing activities:		
Net proceeds from issuance of preferred stock		21,575
Proceeds from exercise of common stock warrant	18	
Proceeds from exercise of preferred stock warrant	4,458	
Payments on notes payable	(10,207)	(2,114)
Net proceeds from issuance of common stock	140,327	162
Repurchase of stock options		(52)
Net cash provided by financing activities	134,596	19,571
Foreign exchange effect on cash and cash equivalents	154	(543)
(Decrease) increase in cash and cash equivalents	101,302	(13,279)
Cash and cash equivalents, beginning of period	37,900	54,221
Cash and cash equivalents, end of period	$ 139,202	$ 40,942
Supplemental information:		
Cash paid for income taxes	65	164
Cash paid for interest	1,275	119
Non cash investing and financing activities		

Issuances of Series E-1 preferred stock warrants		42
Conversion of preferred stock		
Accrued financing costs	407	

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

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CONFORMIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(unaudited)

Note A Organization and Basis of Presentation

ConforMIS, Inc. and subsidiaries (the Company) is a medical technology company that uses its proprietary iFit Image-to-Implant technology platform to develop, manufacture and sell joint replacement implants that are individually sized and shaped, which the Company refers to as customized, to fit each patient s unique anatomy. The Company s proprietary iFit® technology platform is potentially applicable to all major joints. The Company offers a broad line of customized knee implants designed to restore the natural shape of a patient s knee.

The Company was incorporated in Delaware and commenced operations in 2004. The Company introduced its iUni and iDuo in 2007, its iTotal CR in 2011 and its iTotal PS on a limited basis in 2015. The Company has its corporate offices in Bedford, Massachusetts.

Liquidity and operations

Since the Company s inception in June 2004, it has financed its operations through private placements of preferred stock, its initial public offering in July 2015, bank debt and convertible debt financings, equipment purchase loans, and, beginning in 2007, product revenue. The Company s product revenue has continued to grow from year-to-year; however, it has not yet attained profitability and continues to incur operating losses. At September 30, 2015, the Company had an accumulated deficit of $310.4 million.

In November 2014, the Company entered into a senior secured $25 million loan and security agreement with Silicon Valley Bank and Oxford Finance, LLC (the 2014 Secured Loan Agreement), consisting of a revolving line of credit, issued by Silicon Valley Bank (the Revolving Line) of up to $5 million and commitments for two term loans issued jointly by Silicon Valley Bank and Oxford Finance, LLC (the SVB/Oxford Term Loans) of $10 million each. In November 2014, in connection with the Company s entry into the 2014 Secured Loan Agreement, the Company drew down the first $10 million term loan (the SVB/Oxford Term Loan A). Under the 2014 Secured Loan Agreement, the Company could draw down a second $10 million term loan on or prior to November 7, 2015 upon meeting certain conditions. In September 2015, the Company voluntarily prepaid the SVB/Oxford Term Loan A in full and terminated the Company s right to draw down the SVB/Oxford Term Loans and any security interest in favor of Oxford Finance, LLC. The Company retained the Revolving Line. As of September 30, 2015, and December 31, 2014, the Company did not have any revolving loans outstanding under the Revolving Line, with $5 million available for borrowing, subject to the Company meeting certain conditions and based on the Company s borrowing base under the Revolving Line. For further information regarding this facility, see Note K Debt and Notes Payable 2014 Secured Loan Agreement below. The Company expects to incur substantial expenditures in the foreseeable future in connection with the continued expansion of its business.

The Company s principal sources of funds are revenue generated from the sale of its products and the net proceeds from the initial public offering, detailed below.

At September 30, 2015, the Company had cash and cash equivalents and investments of $139.2 million and $0.7 million in restricted cash allocated to lease deposits. At December 31, 2014, the Company had cash and cash equivalents and investments of $37.9 million and $4.4 million in restricted cash allocated to lease deposits and funding for its Asia strategy. See Note L Related Party Transactions for a description of the Asia strategy.

On July 7, 2015, the Company closed its initial public offering (the IPO), of its common stock and issued and sold 10,350,000 shares of its common stock, including 1,350,000 shares of common stock issued upon the exercise in full by the underwriters of their over-allotment option, at a public offering price of $15.00 per share, for aggregate offering proceeds of approximately $155 million. The Company received aggregate net proceeds from the offering of approximately $140 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. The Company s common stock began trading on the NASDAQ Global Select Market on July 1, 2015.

On July 7, 2015, the Company filed a restated certificate of incorporation in connection with its IPO, pursuant to which the Company is authorized to issue 200,000,000 shares of common stock and 5,000,000 shares of preferred stock. In addition, each of the following occurred in connection with the closing of the IPO on July 7, 2015:

- the issuance of the 10,350,000 shares of the Company s common stock;
- the automatic conversion of all outstanding shares of the Company s preferred stock into 25,527,505 shares of common stock;

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- the issuance of 380,902 shares of the Company s common stock upon the exercise or exchange of warrants to purchase the Company s common stock, which consisted of warrants to purchase:

- 4,166 shares of the Company s common stock;
- 252,429 shares of the Company s Series D preferred stock;
- 300,059 shares of the Company s Series E-1 preferred stock; and
- 200,996 shares of the Company s Series E-2 preferred stock;

- the issuance of a warrant to purchase 142,857 shares of the Company s common stock at an exercise price of $7.00 per share in replacement of a warrant to purchase 285,714 shares of the Company s Series C preferred stock at an exercise price of $3.50 per share;
- the conversion of a warrant to purchase 160,000 shares of the Company s Series D preferred stock at an exercise price of $6.00 per share into a warrant to purchase 80,000 shares of common stock at an exercise price of $12.00 per share; and
- the expiration of warrants to purchase 482,964 shares of the Company common stock, which consisted of warrants to purchase:

- 64,217 shares of the Company s Series D preferred stock;
- 215,807 shares of the Company s Series E-1 preferred stock; and
- 202,940 shares of the Company s Series E-2 preferred stock.

In July 2015, upon the closing of the Company s IPO, pursuant to the conditions of the letter agreement in connection with the Company s Asia strategy, $3.5 million of the proceeds received in connection with the sale of the Company s Series E-1 and E-2 preferred stock was reclassified from restricted cash to cash and cash equivalents. See Note L Related Party Transactions .

At September 30, 2015, based on its current operating plan, the Company expects that the net proceeds from its IPO, together with its existing cash and cash equivalents as of September 30, 2015 and anticipated revenue from operations, including from projected sales of its products, will enable it to fund operating expenses and capital expenditure requirements and pay its debt service as it becomes due for at least the next 12 months.

In the event the Company s existing cash and available financing is not sufficient to fund its operations, the Company may need to engage in equity or debt financings to secure additional funds. The Company may not be able to obtain additional financing on terms favorable to the Company, or at all. In addition, the negative covenants under the 2014 Secured Loan Agreement, the pledge of the Company s assets as collateral and the negative pledge with respect to its intellectual property could limit its ability to obtain additional financing.

Basis of presentation and use of estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting periods. The most significant estimates used in these consolidated financial statements include the valuation of accounts receivable, inventory reserves, intangible valuation, equity instruments, impairment assessments, income tax reserves and related allowances, and the lives of property and equipment. Actual results may differ from those estimates. The interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company s Registration Statement on Form S-1 (File No. 333-204384), as amended, which was declared effective by the Securities and Exchange Commission (SEC) on June 30, 2015.

Unaudited Interim Financial Information

The accompanying Interim Consolidated Financial Statements as of September 30, 2015 and for the three and nine months ended September 30, 2015 and 2014, and related interim information contained within the notes to the Consolidated Financial Statements are unaudited. These unaudited interim consolidated financial statements have been prepared in accordance with U.S. GAAP. In management s opinion, the unaudited interim consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments (including normal recurring adjustments) necessary for the fair presentation of the Company s financial position as of September 30, 2015, results of operations for the three and nine months ended September 30, 2015 and 2014, and its cash flows for the nine months ended September 30, 2015 and 2014. The results for the nine months ended September 30, 2015 are not necessarily indicative of the results expected for the full fiscal year or any interim period.

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Note B Summary of Significant Accounting Policies

Concentrations of credit risk and other risks and uncertainties

Financial instruments that subject the Company to credit risk primarily consisted of cash, cash equivalents and accounts receivable. The Company maintains the majority of its cash with accredited financial institutions.

The Company and its contract manufacturers rely on sole source suppliers for certain components. There can be no assurance that a shortage or stoppage of shipments of the materials or components that the Company purchases will not result in a delay in production or adversely affect the Company s business. The Company is in the process of validating alternate suppliers relative to certain key components, which are expected to be phased in during the coming periods.

For the three and nine months ended September 30, 2015 and 2014, no customer represented greater than 10% of revenue. There were no customers that represented greater than 10% of total gross receivable balance at September 30, 2015 or December 31, 2014.

Principles of consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries including ImaTx, Inc., ConforMIS Europe GmbH, ConforMIS UK Limited and ConforMIS Hong Kong Limited. All material intercompany balances and transactions have been eliminated in consolidation.

Cash and cash equivalents

The Company considers all highly liquid investment instruments with original maturities of 90 days or less when purchased, to be cash equivalents. The Company s cash equivalents consisted of demand deposits and money market accounts on deposit with certain financial institutions. Demand deposits are carried at cost which approximates their fair value. Money market accounts are carried at fair value based upon level 1 inputs. See Note C Fair Value Measurements below. The associated risk of concentration is mitigated by banking with credit worthy financial institutions.

The Company had $2.3 million as of September 30, 2015 and $1.2 million as of December 31, 2014 held in foreign bank accounts. In addition, the Company has recorded restricted cash of $0.7 million as of September 30, 2015 and $4.4 million as of December 31, 2014. Restricted cash consists of $0.7 million as of September 30, 2015 and $0.8 million as of December 31, 2014 of security provided for a lease obligation, and $0 million as of September 30, 2015 and $3.6 million as of December 31, 2014 of proceeds received in connection with the sale of Series E-1 and E-2 preferred stock that was contractually restricted for use. See Note L Related Party Transactions below.

Fair value of financial instruments

Certain of the Company s financial instruments, including cash and cash equivalents but excluding money market funds, accounts receivable, accounts payable, accrued expenses and other liabilities are carried at cost, which approximates their fair value because of the short-term maturity. Based on borrowing rates currently available to the Company for loans with similar terms, the carrying value of the Company s long-term debt approximates its fair value.

Accounts receivable and allowance for doubtful accounts

Accounts receivable consisted of amounts due from medical facilities. In estimating whether accounts receivable can be collected, the Company performs evaluations of customers and continuously monitors collections and payments and estimates an allowance for doubtful accounts based on the aging of the underlying invoices, collections experience to date and any specific collection issues that have been identified. The allowance for doubtful accounts is recorded in the period in which revenue is recorded or at the time potential collection risk is identified.

Inventories

Inventories consisted of raw materials, work-in-process components and finished goods. Inventories are stated at the lower of cost, determined using the first-in first-out method, or market value. The Company regularly reviews its inventory quantities on hand and related cost and records a provision for any excess or obsolete inventory based on its estimated forecast of product demand and existing product configurations. The Company also reviews its inventory value to determine if it reflects the lower of cost or market, with market determined based on net realizable value. Appropriate consideration is given to inventory items sold at negative gross margins, purchase commitments and other factors in evaluating net realizable value.

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Property and equipment

Property and equipment is stated at cost less accumulated depreciation and is depreciated using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over their useful life or the life of the lease, whichever is shorter. Assets capitalized under capital leases are amortized in accordance with the respective class of assets and the amortization is included with depreciation expense. Maintenance and repair costs are expensed as incurred.

Intangibles and other long-lived assets

Intangible assets consisted of developed technology and other intellectual property rights licensed from ImaTx as part of the spin-out transaction in 2004. Intangible assets are carried at cost less accumulated amortization.

The Company tests impairment of long-lived assets when events or changes in circumstances indicate that the assets might be impaired. For assets with determinable useful lives, amortization is computed using the straight-line method over the estimated economic lives of the respective intangible assets.

Furthermore, periodically the Company assesses whether long-lived assets, including intangible assets, should be tested for recoverability whenever events or circumstances indicate that their carrying value may not be recoverable.

The amount of impairment, if any, is measured based on fair value, which is determined using estimated undiscounted cash flows to be generated from such assets or group of assets. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, the Company may be required to record impairment charges. During the three and nine months ended September 30, 2015 and 2014, no such impairment charges were recognized.

Goodwill

Goodwill relates to amounts that arose in connection with the acquisition of Imaging Therapeutics, Inc. (formerly known as Osteonet.com, renamed ImaTx, Inc.) in 2009. The Company tests goodwill at least annually for impairment, or more frequently when events or changes in circumstances indicate that the assets may be impaired. This impairment test is performed annually during the fourth quarter at the reporting unit level. Goodwill may be considered impaired if the carrying value of the reporting unit, including goodwill, exceeds the reporting unit s fair value. The Company is comprised of one reporting unit. When testing goodwill for impairment, the Company primarily looks to the fair value of the reporting unit, which is typically estimated using a discounted cash flow approach, which requires the use of assumptions and judgments including estimates of future cash flows and the selection of discount rates. The goodwill recognized upon acquiring ImaTx is not deductible for tax purposes. In light of the voluntary product recall announced by the Company on August 31, 2015 of specific serial numbers of patient-specific instrumentation for the iUni, iDuo and iTotal systems, the Company assessed the potential for impairment of the goodwill carrying value and concluded that the recall did not affect the goodwill. During the three and nine months ended September 30, 2014, there were no triggering events which would require an interim goodwill impairment assessment.

Revenue recognition

The Company generates revenue from the sale of customized implants and instruments to medical facilities through the use of a combination of direct sales personnel, independent sales representatives and distributors in the United States, Austria, Germany, Ireland, the United Kingdom, Switzerland, Hong Kong and Singapore.

Revenue is recognized when all of the following criteria are met:

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

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For a majority of sales to medical facilities, the Company recognizes revenue upon completion of the procedure, which represents satisfaction of the required revenue recognition criteria. For the remaining sales, which are made directly through distributors and generally represent less than 1% of revenue, the Company recognizes revenue at the time of shipment of the product, which represents the point in time when the customer has taken ownership and assumed the risk of loss and the required revenue recognition criteria are satisfied. Such customers are obligated to pay within specified time periods regardless of when or if they ever sell or use the products. Once the revenue recognition criteria have been satisfied the Company does not offer rights of return or price protection and there are no post-delivery obligations.

In April 2015, the Company entered into a fully paid up, worldwide license agreement with Wright Medical Group, Inc., or Wright Group, and its wholly owned subsidiary Wright Medical Technology, Inc., or Wright Technology and collectively with Wright Group, Wright Medical. Under the terms of this license agreement, the Company granted a perpetual, irrevocable, non-exclusive license to Wright Medical to use patient-specific instrument technology covered by the Company s patents and patent applications with off-the-shelf implants in the foot and ankle. This license does not extend to patient-specific implants. This license agreement provided for a single lump-sum payment by Wright Medical to the Company upon entering into the license agreement, which has been paid. This license agreement will expire upon the expiration of the last to expire of the Company s patents and patent applications licensed to Wright Medical, which currently is expected to occur in 2031.

In April 2015, the Company entered into a worldwide license agreement with MicroPort Orthopedics Inc., or MicroPort, a wholly owned subsidiary of MicroPort Scientific Corporation. Under the terms of this license agreement, the Company granted a perpetual, irrevocable, non-exclusive license to MicroPort to use patient-specific instrument technology covered by the Company s patents and patent applications with off-the-shelf implants in the knee. This license does not extend to patient-specific implants. This license agreement provides for the payment to the Company of a fixed royalty percentage of net sales on patient-specific instruments and associated implant components in the knee, including MicroPort s Prophecy patient-specific instruments used with its Advance and Evolution implant components. This license agreement also provided for a single lump-sum payment by MicroPort to the Company upon entering into the license agreement, which has been paid. This license agreement will expire upon the expiration of the last to expire of the Company s patents and patent applications licensed to MicroPort, which currently is expected to occur in 2029.

The Company has accounted for the agreements with Wright Medical and MicroPort under ASC 605-25, Multiple-Element Arrangements and Staff Accounting Bulletin No. 104, Revenue Recognition (ASC 605). In accordance with ASC 605, the Company is required to identify and account for each of the separate units of accounting. The Company identified the relative selling price for each and then allocated the total consideration based on their relative values. In connection with these agreements, in April 2015, the Company recognized in aggregate (i) back-owed royalties of $3.4 million as royalty revenue and (ii) the value attributable to the settlements of $0.2 million as other income. Additionally, the Company recognized an initial $5.1 million in aggregate as deferred royalty revenue, which is recognized as royalty revenue ratably through 2031. See Note I Deferred Revenue . The on-going royalty from MicroPort is recognized as royalty revenue upon receipt of payment.

Shipping and handling costs

Amounts invoiced to customers for shipping and handling are classified as revenue. Shipping and handling costs incurred are included in general and administrative expense. Shipping and handling expense was $0.5 million and $0.4 million for the three months ended September 30, 2015 and 2014, respectively, and was $2.1 million and $1.1 million for the nine months ended September 30, 2015 and 2014, respectively.

Taxes collected from customers and remitted to government authorities

The Company s policy is to present taxes collected from customers and remitted to government authorities on a net basis and not to include tax amounts in revenue.

Research and development expense

The Company s research and development costs consisted of engineering, product development, quality assurance, clinical and regulatory expense. These costs are primarily related to employee compensation, including salary, benefits and stock-based compensation. The Company also incurs costs related to consulting fees, materials and supplies, and marketing studies, including data management and associated travel expense. Research and development costs are expensed as incurred.

Advertising expense

Advertising costs are expensed as incurred. Advertising expense was approximately $41,000 and $43,000 for the three months ended September 30, 2015 and 2014, respectively, and was $0.2 million and $0.3 million for the nine months ended September 30, 2015 and 2014, respectively.

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Segment reporting

Operating segments are defined as components of an enterprise about which separate financial information is available and is evaluated on a regular basis by the chief operating decision-maker, or decision-making group, in deciding how to allocate resources to an individual segment and in assessing performance of the segment. The Company s chief operating decision-maker is its chief executive officer. The Company s chief executive officer reviews financial information presented on an aggregate basis for purposes of allocating resources and evaluating financial performance. The Company has one business activity and there are no segment managers who are held accountable for operations, operating results and plans for products or components below the aggregate Company level. Accordingly, in light of the Company s current product offerings, management has determined that the primary form of internal reporting is aligned with the offering of the ConforMIS customized joint replacement products and that the Company operates as one segment. See Note O Segment and Geographic Data .

Comprehensive loss

At September 30, 2015 and December 31, 2014, accumulated other comprehensive loss consists of foreign currency translation adjustments.

Foreign currency translation and transactions

The assets and liabilities of the Company s foreign operations are translated into U.S. dollars at current exchange rates at the balance sheet date, and income and expense items are translated at average rates of exchange prevailing during the year. Gains and losses realized from transactions denominated in foreign currencies, including intercompany balances not considered permanent investments, are included in the consolidated statements of operations.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses and tax credit carry forwards.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period that includes the enactment date.

The tax benefit from an uncertain tax position is only recognized if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial

statements from these positions are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution.

The Company reviews its tax positions on an annual basis and more frequently as facts surrounding tax positions change. Based on these future events, the Company may recognize uncertain tax positions or reverse current uncertain tax positions, the impact of which would affect the consolidated financial statements.

Medical device excise tax

The Company is subject to the Health Care and Education Reconciliation Act of 2010 (the Act), which imposes a tax equal to 2.3% on the sales price of any taxable medical device by a medical device manufacturer, producer or importer of such device. Under the Act, a taxable medical device is any device defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, intended for humans, which includes an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which meets certain requirements. The Company incurred medical device excise tax expense of $0.2 million for the three months ended September 30, 2015 and 2014, respectively, and $0.6 million and $0.4 million for the nine months ended September 30, 2015 and 2014, respectively. Medical device tax is included in general and administrative expense.

Stock-based compensation

The Company accounts for stock-based compensation in accordance with ASC 718, Stock Based Compensation. ASC 718 requires all stock-based payments to employees and consultants, including grants of stock options, to be recognized in the consolidated statements of operations based on their fair values. The Company uses the Black-Scholes option pricing model to

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determine the weighted-average fair value of options granted and recognizes the compensation expense of stock-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of stock-based payment awards utilizing the Black-Scholes option pricing model is affected by the stock price, exercise price, and a number of assumptions, including expected volatility of the stock, expected life of the option, risk-free interest rate and expected dividends on the stock. The Company evaluates the assumptions used to value the awards at each grant date and if factors change and different assumptions are utilized, stock-based compensation expense may differ significantly from what has been recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense.

The stock price for option grants are set by the Company s board of directors and, prior to the Company s IPO in July 2015, were based upon guidance set forth by the American Institute of Certified Public Accountants, or AICPA, in its Technical Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation* . To that end, the board considered a number of factors in determining the option price, including: (1) past sales of the Company s convertible preferred stock, and the rights, preferences and privileges of the Company stock, (2) obtaining FDA 510(k) clearance, and (3) achievement of budgeted results. See Note M Stockholders Equity for a summary of the stock option activity under the Company s stock-based compensation plan.

Net loss per share

The Company calculates net loss per share in accordance with Accounting Standards Codification 260, Earnings per Share. Basic earnings per share (EPS) is calculated by dividing the net income or loss for the period by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents.

Diluted EPS is computed by dividing the net income or loss for the period by the weighted average number of common shares outstanding for the period and the weighted average number of dilutive common stock equivalents outstanding for the period determined using the treasury stock method.

The following table sets forth the computation of basic and diluted earnings per share attributable to stockholders (in thousands, except share and per share data):

(in thousands, except share and per share data)	Three Months Ended September 30, 2015	2014	Nine Months Ended September 30, 2015	2014
Numerator:				
Numerator for basic and diluted loss per share:				
Net loss	$ (17,107)	$ (10,396)	$ (42,256)	$ (33,592)
Denominator:				
Denominator for basic loss per share:				
Weighted average shares	37,933,069	4,267,148	15,688,686	4,224,454

Basic loss per share attributable to ConforMIS, Inc. stockholders	$ (0.45)	$ (2.44)	$ (2.69)	$ (7.95)
Diluted loss per share attributable to ConforMIS, Inc. stockholders	$ (0.45)	$ (2.44)	$ (2.69)	$ (7.95)

The following table sets forth potential shares of common stock equivalents that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Series A Preferred	129,739	1,705,138	1,172,282	1,705,138
Series B Preferred	170,029	2,234,668	1,536,334	2,234,668
Series C Preferred	186,643	2,453,018	1,686,450	2,453,018
Series D Preferred	508,895	6,651,562	4,576,684	6,558,201
Series E-1 Preferred	556,709	6,718,860	5,030,261	6,269,004
Series E-2 Preferred	390,295	5,129,590	3,526,593	5,129,590
Series C Preferred Warrants		48,938		48,938
Series D Preferred Warrants		38,164		38,164
Series E-2 Preferred Warrants		11,354		11,354
Common stock warrants		2,158	329,348	2,158
Stock options	3,887,561	3,745,598	3,880,463	3,565,146
Total	5,829,870	28,739,047	21,738,415	28,015,379

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Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606) . ASU No. 2014-09 outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new guidance was to be effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2017; early adoption was permitted for annual reporting periods beginning after December 15, 2016, including interim reporting periods within those annual periods. Companies have the option of using either a full retrospective or a modified retrospective approach to adopt the guidance. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of the guidance contained in ASU 2014-09 by one year. Thus, the guidance is effective for the Company commencing in the first quarter of 2019. The Company does not expect that the adoption of ASU 2014-09 will have a material effect on its consolidated financial statements.

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

In April 2015, the FASB issued ASU No. 2015-05, Intangibles Goodwill and Other Internal-Use Software (Subtopic 350-40): Customer s Accounting for Fees Paid in a Cloud Computing Arrangement (ASU 2015-05), which provides guidance to clarify the customer s accounting for fees paid in a cloud computing arrangement. This guidance is effective for annual periods and interim reporting periods of public entities beginning after December 15, 2015. The Company does not expect that the adoption of ASU 2015-05 will have a material effect on its consolidated financial statements.

In August 2014, FASB issued ASU No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40) Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern (ASU 2014-15). This newly issued accounting standard provides guidance about management s responsibility to evaluate whether there is a substantial doubt about an entity s ability to continue as a going concern and to provide related footnote disclosures. The defined term substantial doubt requires an evaluation of every reporting period including interim periods, provides principles for considering the mitigating effect of management s plans, requires certain disclosures when substantial doubt is alleviated as a result of consideration of management s plans, requires an express statement and other disclosures when substantial doubt is not alleviated, and requires an assessment for a period of one year after the date that the financial statements are issued or available to be issued. The amendments in ASU 2014-15 are effective for annual periods beginning after December 15, 2016 and interim periods within those reporting periods. Earlier adoption is permitted. The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements.

Note C Fair Value Measurements

The Fair Value Measurements topic of the FASB Codification establishes a framework for measuring fair value in accordance with US GAAP, clarifies the definition of fair value within that framework and expands disclosures about fair value measurements. This guidance requires disclosure regarding the manner in which fair value is determined for assets and liabilities and establishes a three-tiered value hierarchy into which these assets and liabilities must be grouped, based upon significant levels of inputs as follows:

Level 1 Quoted prices in active markets for identical assets or liabilities.

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Level 2 Observable inputs, other than Level 1 prices, such as quoted prices in active markets for similar assets and liabilities, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

The only assets and liabilities subject to fair value measurement standards at September 30, 2015 and December 31, 2014 are money market funds that are cash equivalents based on Level 1 inputs. The values of these funds were $126.8 million as of September 30, 2015 and $30,000 as of December 31, 2014.

Note D Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Total receivables	$ 8,626	$ 9,281
Allowance for doubtful accounts and returns	(366)	(162)
Accounts receivable, net	$ 8,260	$ 9,119

Write-offs related to accounts receivable were approximately $24,000 and $88,000 for the three and nine months ended September 30, 2015, respectively, and $0 and $0.02 million for the three and nine months ended September 30, 2014, respectively.

Note E Inventories

Inventories consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Raw Material	$ 5,260	$ 3,311
Work in process	2,719	1,282
Finished goods	2,685	3,098
Total Inventories	$ 10,664	$ 7,691

At September 30, 2015, inventories include write-downs of $0.9 million and reserves of $0.2 million for estimated surgery cancellations both related to units affected by the recall and sterilization capacity limitation during the month of September.

Note F Property and Equipment

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

	Estimated Useful Life (Years)	September 30, 2015	December 31, 2014
Equipment	5-7	$ 11,548	$ 9,598
Furniture and fixtures	5-7	390	362
Computer and software	3	4,948	3,725
Leasehold improvements	2-7	1,462	1,040
Total property and equipment		18,348	14,725
Accumulated depreciation		(7,693)	(6,029)
Property and equipment, net		$ 10,655	$ 8,696

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Depreciation expense related to property and equipment was $0.6 million and $0.5 million for the three months ended September 30, 2015 and 2014, $1.7 million and $1.4 million for the nine months ended September 30, 2015 and 2014, respectively.

Note G Intangible Assets

The components of intangible assets consisted of the following (in thousands):

	Estimated Useful Life (Years)	September 30, 2015 (unaudited)	December 31, 2014
Developed technology	10	$ 979	$ 979
Accumulated amortization		(558)	(485)
Developed technology, net		421	494
License agreements	10	1,508	1,508
Accumulated amortization		(872)	(759)
License technology, net		636	749
Intangible assets, net	10	$ 1,057	$ 1,243

The Company recognized amortization expense of $62,000 in the three months ended September 30, 2015 and 2014, and $186,000 in the nine months ended September 30, 2015 and 2014. The weighted-average remaining life of total amortizable intangible assets is 4.25 years for the developed technology and license agreements.

The estimated future aggregated amortization expense for intangible assets owned as of September 30, 2015 consisted of the following (in thousands):

	Amortization expense
2015 (remainder of year)	$ 63
2016	249
2017	249
2018	249
2019	247
	$ 1,057

Note H Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Accrued employee compensation	$ 3,278	$ 2,125
Accrued financing costs	407	
Deferred rent	208	277
Accrued legal expense	517	265
Accrued consulting expense	83	139
Accrued vendor charges	332	932
Accrued revenue share expense	687	727
Accrued patent settlement and license costs	500	750
Accrued clinical trial expense	210	211
Accrued other	731	1,516
	$ 6,953	$ 6,942

Note I Deferred Revenue

In connection with the license agreements the Company entered into in April 2015 with Wright Medical and MicroPort (see Note B Summary of Significant Accounting Policies), the Company recognized an initial $5.1 million in aggregate as deferred royalty revenue, of which $4.9 million and $0.2 million is recognized as royalty revenue ratably through 2031 and 2029, respectively.

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Note J Commitments and Contingencies

Operating Leases

The Company maintains its corporate headquarters in a leased building located in Bedford, Massachusetts, and in July 2015 moved its manufacturing from a facility located in Burlington, Massachusetts to a facility located in Wilmington, Massachusetts, all of which are accounted for as operating leases.

The Company leases the Bedford facility under a long-term, non-cancellable sublease that is scheduled to expire in April 2017. The Wilmington facility is leased under a long-term, non-cancellable lease that commenced in April 2015 and will expire in March 2022. The Company leased the Burlington facility under a long-term, non-cancellable lease that was set to expire in October 2015. In June 2014, the Company entered into a termination agreement to terminate the Burlington facility lease as of July 31, 2015. Accordingly, all monetary obligations pursuant to the original lease are prorated through the termination date and deferred rent and depreciation of leasehold improvements expense were accelerated. In July 2015, the Company and the landlord of the Burlington facility agreed to a hold over for 30 days beyond the lease termination of July 31, 2015 through August 31, 2015. The Company also leases satellite facilities under short-term non-cancellable operating leases.

The future minimum rental payments under the Company s non-cancellable operating leases as of September 30, 2015 are as follows (in thousands):

Year		Minimum lease Payments
2015 remainder of year	$	377
2016		1,615
2017		789
2018		364
2019-2022		1,253
	$	4,398

Rent expense of $0.5 million and $0.4 million was charged to operations for the three months ended September 30, 2015 and 2014, respectively, and $1.3 million and $1.2 million for the nine months ended September 30, 2015 and 2014. The Company s operating lease agreements contain scheduled rent increases, which are being amortized over the terms of the agreements using the straight-line method. Deferred rent was $0.4 million as of September 30, 2015 and $0.5 million as of December 31, 2014. Deferred rent is included in accrued expenses and other long-term liabilities.

License and revenue share agreements

Settlement and patent license

In December 2014, the Company entered into a settlement and patent license agreement that grants ConforMIS a fully paid-up license to certain intellectual property and provides for the mutual release and absolute discharge of any and all claims in connection with the licensed patents and with suits filed by and against the parties to the agreement in exchange for $750,000 payable by the Company in two installments, wherein the first installment of $250,000 is payable in January of 2015 and the second installment of $500,000 is payable no later than December 1, 2015. The Company expensed the full amount of the consideration in 2014, included in general and administrative expense. The license continues until the expiration of the last patent.

Revenue share agreements

The Company is party to revenue share agreements with certain past and present members of its scientific advisory board under which these advisors agreed to participate on its scientific advisory board and to assist with the development of the Company s customized implant products and related intellectual property. These agreements provide that the Company will pay the advisor a specified percentage of the Company s net revenues, ranging from 0.2% to 1.33%, with respect to the Company s products on which the advisor made a technical contribution or, in some cases, which the Company covered by a claim of one of its patents on which the advisor is a named inventor. The specific percentage is determined by reference to product classifications set forth in the agreement and is tiered based on the level of net revenues collected by the Company on such product sales. The Company s payment obligations under these agreements typically expire a fixed number of years after expiration or termination of the agreement, but in some cases

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expire on a product-by-product basis or expiration of the last to expire of the Company s patents where the advisor is a named inventor that claims the applicable product.

Philipp Lang, M.D., the Company s Chief Executive Officer, joined the Company s scientific advisory board in 2004 prior to becoming an employee. The Company first entered into a revenue share agreement with Dr. Lang in 2008 when he became the Company s Chief Executive Officer. In 2011, the Company entered into an amended and restated revenue share agreement with Dr. Lang. Under this agreement, the specified percentage of the Company s net revenues payable to Dr. Lang ranges from 0.875% to 1.33% and applies to all of the Company s current and planned products, including the Company s iUni, iDuo, iTotal Cr, iTotal PS and iTotal Hip products, as well as certain other knee, hip and shoulder replacement products and related instrumentation the Company may develop in the future. The Company s payment obligations under this agreement expire on a product-by-product basis on the last to expire of the Company s patents on which Dr. Lang is named an inventor that claim the applicable product. These payment obligations survive termination of Dr. Lang s employment with the Company.

The Company incurred aggregate revenue share expense, including all amounts payable under the Company s scientific advisory board and Chief Executive Officer revenue share agreements of $0.7 million during the three months ended September 30, 2015, representing 5.1% of product revenue, $0.6 million during the three months ended September 30, 2014, representing 5.2% of product revenue, $2.2 million during the nine months ended September 30, 2015, representing 5.1% of product revenue, and $1.5 million during the nine months ended September 30, 2014, representing 4.5% of product revenue. See Note L Related Party Transactions for further information regarding the Company s arrangement with its Chief Executive Officer.

Other obligations

In the ordinary course of business, the Company is a party to certain non-cancellable contractual obligations typically related to research and development and marketing services. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Legal proceedings

In the ordinary course of conducting its business, the Company is subject to litigation, claims and administrative proceedings on a variety of matters. An estimate of the possible loss or range of loss as a result of any of these matters cannot be made; however, management does not believe that these matters, individually or in the aggregate, are material to its financial condition, results of operations or cash flows.

In September 2015, a class action lawsuit was filed against the Company and certain of the Company s officers on behalf of stockholders who purchased the Company s common stock in connection with the IPO or on the open market between July 1, 2015 and August 28, 2015 alleging that statements made were false and misleading because the Company s manufacturing processes were flawed and, as a result of such flaws, a number of the Company s knee replacement product systems were defective. The complaint seeks, among other relief, class certification of the lawsuit, unspecified compensatory damages, interest, attorneys fees, expert fees and other costs. The Company believe it has valid defenses to the claims in the lawsuit, will deny liability and intends to defend itself vigorously. The Company is presently unable to predict the outcome of the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit.

In October 2015, a complaint for patent infringement was filed against the Company alleging that the Company s iUni G2 and iDuo G2 partial knee replacement surgical techniques infringe one or more claims of United States Patent No. 6,575,980. The plaintiff seeks damages, including for willful infringement, attorney s fees, costs and a permanent injunction. The Company believes that none of its products or services infringes the plaintiff s patent. The Company intends to deny liability and to defend itself vigorously. The Company is presently unable to predict the outcome of the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit.

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. In accordance with its bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company s request in such capacity. There have been no claims to date and the Company has a director and officer insurance policy that enables it to recover a portion of any amounts paid for future claims.

Note K Debt and Notes Payable

Long-term debt consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Massachusetts Development Finance Agency	$ 552	$ 760
Oxford Finance, LLC		6,250
Silicon Valley Bank		3,750
	552	10,760
Less total discount	(5)	(140)
	547	10,620
Less current installments	289	272
Long-term debt, excluding current installments	$ 258	$ 10,348

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The principal payments due as of September 31, 2015 consisted of the following (in thousands):

	Principal Payment
2015 (remainder of year)	$ 71
2016	299
2017	182
Total	$ 552

2014 Secured Loan Agreement

On November 7, 2014, or the effective date, the Company entered into the 2014 Secured Loan Agreement consisting of the Revolving Line of up to $5 million (subject to availability under the borrowing base and satisfaction of other funding conditions), and commitments for the two $10 million SVB/Oxford Term Loans. At the time the Company entered into the 2014 Secured Loan Agreement, it borrowed the first $10 million term loan, or the SVB/Oxford Term Loan A, and issued the lenders warrants to purchase 33,481 shares of the Company s common stock. On September 8, 2015, the Company voluntarily prepaid the SVB/Oxford Term Loan A and terminated the Company s right to draw down the SVB/Oxford Term Loans and any security interest in the Company s assets in favor of Oxford Finance, LLC. The Company retained the Revolving Line with Silicon Valley Bank. Prior to repaying the SVB/Oxford Term Loan A, the Company was eligible to borrow a second term loan in a principal amount of $10 million (the SVB/Oxford Term Loan B), on or prior to November 7, 2015, upon meeting certain conditions, including the Company being able to make certain agreed upon representations and warranties to the lenders and a determination by the lenders, in their sole discretion, that there has been no occurrence of any material adverse change, as defined in the 2014 Secured Loan Agreement, or any material deviation from the annual financial projections provided by the Company and accepted by the lenders. In the event that the Company had borrowed the additional $10 million term loan, the Company would have been obligated to issue warrants to purchase an additional 33,481 shares of its common stock to the lenders under the 2014 Secured Loan Agreement.

Unless earlier terminated by the Company or accelerated by the lender, the Revolving Line terminates on November 7, 2019, with all outstanding borrowings and associated interest becoming due and payable upon such termination. The Company s ability to borrow under the Revolving Line is subject to a borrowing base, calculated as 85% (or such lower percent as Silicon Valley Bank may determine as prescribed in the 2014 Secured Loan Agreement) of eligible accounts receivable. Borrowings under the Revolving Line bear interest at a floating per annum rate equal to the prime rate. Interest on the Revolving Line is payable monthly. In addition to interest, the Company is obligated to pay a $250,000 fee for the Revolving Line, which is payable in annual increments of $50,000 due on the effective date and each anniversary of the effective date. The Company will amortize this fee ratably over the term of the Revolving Line.

Further, the Company is obligated to pay a termination fee of $100,000 if it elects to terminate the Revolving Line prior to the first anniversary of the effective date, or $50,000 if it elects to terminate the Revolving Line between the first and third anniversaries of the effective date, provided that no termination fee will be payable if the Revolving Line is replaced with a new facility or an amended and restated facility from Silicon Valley Bank.

Prior to the prepayment of the SVB/Oxford Term Loan A, the SVB/Oxford Term Loans each had a maturity date of November 1, 2019 (the Term Loan Maturity Date). The SVB/Oxford Term Loan A bore interest at a fixed rate of 7.25% per annum, which rate was determined as the prime rate on the original date of funding plus 4%. The Company never borrowed the SVB/Oxford Term Loan B. If the Company had borrowed the SVB/Oxford Term Loan B, such term loan would have accrued interest at a fixed per annum rate equal to the prime rate on the date of

funding, plus 4%. Interest on each of the SVB/Oxford Term Loans was payable monthly in arrears. After an interest only period, the Company was required to make equal monthly payments of principal and interest, in arrears, for the remaining term until maturity. In addition to interest, the Company was obligated to make a final payment fee equal to the original principal amount of the applicable SVB/Oxford Term Loan, multiplied by 7%, which was paid by the Company with the term loan prepayment, and had been ratably expensed to interest while the loan was outstanding using the effective interest method. Further, the Company was required to pay a prepayment fee equal to 3% of the principal amount being prepaid.

The Company s obligations under the Revolving Line are secured by a security interest over substantially all of the Company s and ImaTx s assets, other than intellectual property, with respect to which the Company and ImaTx granted a negative pledge. The 2014 Secured Loan Agreement contains negative covenants restricting its activities, including limitations on dispositions, mergers or acquisitions, incurring indebtedness or liens, paying dividends or making investments and certain other business transactions. There are no financial covenants associated with the 2014 Secured Loan Agreement. Obligations under the 2014 Secured Loan Agreement are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the business, operations or financial or other condition.

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Also, immediately upon the occurrence and during the continuance of an event of default, all obligations outstanding under the agreement shall accrue interest at a fixed rate equal to the per annum rate that is otherwise applicable thereto plus 5%.

As of September 30, 2015 and December 31, 2014, no advances were outstanding from the fully available $5 million Revolving Line. Administrative and legal costs in connection with the 2014 Secured Loan Agreement were deemed immaterial and expensed as incurred.

In connection with the SVB/Oxford Term Loan A, the Company issued warrants to purchase an aggregate of 33,481 shares of the Company s common stock at a price of $8.96 per share, which was the fair value of the Company s common stock. Based on the Company s assessment of the warrants relative to ASC 480, *Distinguishing Liabilities from Equity*, the warrants are classified as equity and the Company recorded $134,000 fair value of the warrants as a discount to the term loan recorded to additional paid-in capital.

The value of the warrants was amortized to interest expense while the term loan was outstanding with the remaining amount fully expensed at the time of the repayment. The Company used the Black-Scholes option pricing model to calculate the fair value of the warrants based on the following inputs and assumptions:

Risk-free interest rate	1.6%
Expected term (in years)	5
Dividend yield	0%
Expected volatility	50%

$15 million term loan WTI Term Loan II

In May 2014, the $15 million term loan and security agreement (the WTI Term Loan II) entered into with Western Technology Investment in February 2011 was paid-off as scheduled. The 39-month credit facility was secured by certain tangible assets of the Company and included a security interest in the Company s intellectual property. The borrowings under the WTI Term Loan II, which were drawn in tranches, incurred a fixed interest rate of 12.50% per annum. Following the interest only periods, interest and principal was payable in equal monthly installments. In 2011, the Company drew down two tranches of $5 million each and issued warrants to purchase $1,100,000 and $80,000 of Series D preferred stock. Based on the Company s assessment of the warrants relative to ASC 480, *Distinguishing Liabilities from Equity*, the warrants are classified as equity and the Company recorded $573,000 million and $76,000 fair value of the warrants as a discount to the term loan recorded to additional paid-in capital. The value of the warrants was amortized to interest expense over the life of the term loans, which was fully amortized when the loan was paid in full in 2014.

Additionally, in July 2011, in connection with an amendment of the WTI Term Loan II to extend the termination dates of the second and third tranches, the Company issued a warrant to purchase $159,000 of Series D preferred stock or equivalent preferred stock. Based on the Company s assessment of the warrants relative to ASC 480, *Distinguishing Liabilities from Equity*, the warrants are classified as equity and the Company recorded $79,000 fair value of the warrants as a discount to the term loan to additional paid-in capital. The value of the warrants was amortized to interest expense over the remaining life of the term loan which was fully amortized when the loan was paid-off.

$1.4 million term loan Massachusetts Development Finance Agency

In June 2011, the Company entered into a $1.4 million term loan facility with Massachusetts Development Finance Agency (MDFA) for the purposes of equipment purchases. The MDFA facility, which is subordinated to the SVB/Oxford Term Loans and any advances under the Revolving Line, are secured on a second-lien basis by certain tangible assets of the Company.

At the time the Company entered into the MDFA facility, the Company borrowed the first tranche of $0.6 million, with the remaining funds to be borrowed over the following 18 months. To date, the Company has borrowed a total of $1.4 million of the available commitments under the facility, of which $522,000 in loans were outstanding as of September 30, 2015. Loans under the MDFA facility bear a fixed interest rate of 6.5% per annum. Interest is payable monthly in arrears. Beginning on January 1, 2013, the Company began making payments of principal and interest in 66 equal monthly installments.

In connection with the MDFA facility, the Company issued warrants to MDFA to purchase 16,000 shares of Series D preferred stock. Based on the Company s assessment of the warrants relative to ASC 480, *Distinguishing Liabilities from Equity*, the warrants are classified as equity and the Company recorded fair value of $46,000 as a discount to the term loan and was amortized to interest expense over the 84-month life of the term loan.

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Note L Related Party Transactions

Vertegen

In April 2007, the Company entered into a license agreement with Vertegen, Inc., or Vertegen, which was amended in May 2015 (the Vertegen Agreement). Vertegen is an entity that is wholly owned by Dr. Lang, the Company s Chief Executive Officer. Under the Vertegen Agreement, Vertegen granted the Company an exclusive, worldwide license under specified Vertegen patent rights and related technology to make, use and sell products and services in the fields of diagnosis and treatment of articular disorders and disorders of the human spine. The company may sublicense the rights licensed to it by Vertegen. The Company is required to use commercially reasonable efforts, at its sole expense, to prosecute the patent applications licensed to the Company by Vertegen.

In connection with entering into the license agreement with Vertegen, the Company paid Vertegen an initial license fee of $10,000 and issued Vertegen a warrant to purchase 100,000 shares of its common stock at an exercise price of $1.10 per share, which has expired unexercised. Pursuant to the Vertegen Agreement, the Company is required to pay Vertegen a 6% royalty on net sales of products covered by the patents licensed to us by Vertegen, the subject matter of which is directed primarily to spinal implants, and any proceeds from the Company enforcing the patent rights licensed to the Company by Vertegen. Such 6% royalty rate will be reduced to 3% in the United States during the five-year period following the expiration of the last-to-expire applicable patent in the United States and in the rest of the world during the five-year period following the expiration of the last-to-expire patent anywhere in the world. The Company has not sold any products subject to this agreement and has paid no royalties under this agreement. The Company has paid approximately $140,000 in expenses as of September 30, 2015 in connection with the filing and prosecution of the patent applications licensed to the Company by Vertegen.

The Vertegen Agreement may be terminated by the Company at any time by providing notice to Vertegen. In addition, Vertegen may terminate the Vertegen Agreement in its entirety if the Company is in material breach of the agreement, and the Company fails to cure such breach during a specified period.

Asia strategy

In connection with the issuance and sale of the Company s Series E-1 and Series E-2 preferred stock, the Company entered into a letter agreement with an investor that provides that $5.0 million of the proceeds received by the Company from the investor for the sale of the Company s Series E-1 and Series E-2 preferred stock could only be used in connection with the marketing and sale of the Company s products in Asia and that a committee of the Company s board of directors should be formed for the purposes of directing and overseeing the investment of such proceeds. This letter agreement terminated upon the closing of the Company s IPO. Upon the termination of this letter agreement, the Company was no longer required to invest such proceeds in the manner that had been required by the letter agreement and it is not required to maintain such an Asia strategy committee. While the Company is not obligated to maintain such a committee, the Company s board of directors has determined to continue to have such a committee for a period of two years from the closing of its IPO.

In July 2013, the Company agreed to exchange 381,875 shares of Series E-1 preferred stock held by the investor for 381,875 shares of the Company s Series E-2 preferred stock.

Based on the restriction on the use of the proceeds received in connection with the letter agreement, the proceeds were classified as restricted cash and an investment activity. Upon the closing of the Company s IPO in July 2015, pursuant to the conditions of the letter agreement in connection with the Asia strategy, $3.5 million of the proceeds received in connection with the letter agreement were reclassified from restricted cash to cash and cash equivalents. As of September 30, 2015, $0 million of the proceeds, and as of December 31, 2014, $3.6 million of the proceeds were included in restricted cash.

Revenue share agreement

As described in Note J, the Company is a party to certain agreements with advisors to participate as a member of the Company s scientific advisory board. In September 2011, the Company entered into an amended and restated revenue share agreement with Philipp Lang, M.D., the Company s Chief Executive Officer, which amended and restated a similar agreement entered into in 2008 when Dr. Lang stepped down as chair of the Company s scientific advisory board and became the Company s Chief Executive Officer. This agreement provides that the Company will pay Dr. Lang a specified percentage of our net revenues, ranging from 0.875% to 1.33%, with respect to all of our current and planned products, including the Company s iUni, iDuo, iTotal CR, iTotal PS and iTotal Hip products, as well as certain other knee, hip and shoulder replacement products and related instrumentation the Company may develop in the future. The specific percentage is determined by reference to product classifications set forth in the agreement and is tiered based on the level of net revenues collected by the Company on such product sales. The Company s payment obligations expire on a product-by-product basis on the last to expire of the Company s patents on which Dr. Lang is a named inventor that claim the applicable product. These payment obligations survive any termination of Dr. Lang s employment with the Company. The Company incurred revenue share expense paid to Dr. Lang of $0.2 million and $0.5 million for the three and nine months ended

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September 30, 2015, respectively, and $0.1 million and $0.4 million for the three and nine months ended September 30, 2014, respectively.

Note M Stockholders Equity

Common stock

On June 16, 2015, the Company effected a reverse stock split of the Company s common stock at a ratio of one share for every two shares previously held, and a proportional adjustment to the existing conversion ratios for each series of preferred stock. All common stock share and common stock per share data included in these financial statements reflect the reverse stock split.

On July 7, 2015 the Company closed its IPO, which resulted in the sale of 10,350,000 shares of its common stock at a public offering price of $15.00 per share. Upon closing of the IPO, all outstanding shares of the Company s preferred stock were automatically converted into 25,904,241 shares of common stock. Additionally upon closing of the IPO, the Company adopted a restated certificate of incorporation increasing the number of authorized shares of its common stock to 200,000,000 shares.

Common stockholders are entitled to dividends as and when declared by the board of directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. The holder of each share of common stock was entitled to one vote.

Summary of common stock activity is as follows:

	Shares
Outstanding December 31, 2014	4,286,164
Issuance of common stock - option & warrant exercises	154,084
Issuance of restricted common stock	14,666
Issuance of common stock - IPO	10,350,000
Issuance of common stock - preferred stock conversion to common stock	25,904,241
Outstanding September 30, 2015 (unaudited)	40,709,155

Preferred stock

Prior to the filing of the Company s Restated Certificate of Incorporation upon closing if its IPO, the Company was authorized to issue 53,496,241 shares of $0.00001 par value preferred stock. The Company s Restated Certificate of Incorporation authorizes the

Company to issue 5,000,000 shares of preferred stock, $0.00001 par value, all of which is undesignated.

At December 31, 2014, convertible preferred stock consisted of the following (in thousands, except share data):

Series	Shares Authorized	Shares Issued and Outstanding		Liquidation Value
Series A convertible preferred	3,410,278	3,410,278	$	3,410
Series B convertible preferred	4,469,349	4,469,349		12,023
Series C convertible preferred	5,191,754	4,906,040		17,171
Series D convertible preferred	14,612,360	13,307,287		79,844
Series E-1 convertible preferred	15,149,375	14,633,509		117,068
Series E-2 convertible preferred	10,663,125	10,259,189		123,110
	53,496,241	50,985,652	$	352,626

Prior to the conversion to common stock, the significant terms of the Company s preferred stock were as follows:

Conversion. Each share of preferred stock was convertible into the Company s common stock at the option of the holder on a two-to-one basis. Additionally, each share of preferred stock was automatically convertible into common stock upon the earlier (1) closing of a firm commitment underwritten public offering from which the aggregate net proceeds equal or exceed $50.0 million and in which the price per share is at least $20.00, or the equivalent price after adjustment for certain events, (2) with respect to the Series A preferred stock, approval of the holders of a majority of the outstanding Series A preferred stock, (3) with respect to the Series B preferred stock, approval of the holders of a majority of the outstanding Series B preferred stock, (4) with respect to the Series C preferred stock, approval of the holders of a majority of the outstanding Series C preferred stock, (5) with respect to the Series D preferred stock, approval of the holders of a majority of the outstanding Series D preferred stock, (6) with respect to the Series E-1 preferred stock, approval of the holders of a majority of the outstanding Series E-1 preferred stock, and (7) with respect to the Series E-2 preferred stock, approval of the holders of a majority of the outstanding Series E-2 preferred stock.

Antidilution Protection. The rate at which shares of preferred stock were convertible into common stock was subject to adjustment for stock dividends, stock splits, reverse stock splits, and similar events. The rate also was subject to broad-based weighted average antidilution protection, subject to exclusions for: (1) the issuance of common stock as approved by the Board of Directors to directors, officers, employees, consultants, and advisors, (2) the issuance of the Company s capital stock (or rights therefor) in connection with acquisitions and mergers as approved by the Board of Directors, (3) the issuance of the Company s capital stock (or rights therefor) as approved by the Board of Directors in connection with equipment leasing, real estate, bank financing, or similar transactions, (4) the issuance of the Company s capital stock (or rights therefor) as approved by the Board of Directors to vendors, customers or strategic business partners, (5) common stock issued upon conversion of preferred stock, (6) the issuance of securities in

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an underwritten public offering pursuant to an effective registration statement, (7) the issuance of securities pursuant to outstanding warrants as of July 5, 2013, (8) issuances of securities approved by the holders of a majority of the outstanding Series E-1 preferred stock and outstanding Series E-2 preferred stock, voting together as a single class on an as-converted basis, and either unanimously approved by the Company s Board of Directors or the holders of outstanding shares of preferred stock, voting together as a single class on an as-converted basis, and (9) Series E-1 preferred stock or Series E-2 preferred stock issued or issuable at a purchase price equal to or greater than $8.00 per share.

Dividends. The holders of preferred stock were entitled to receive non-cumulative and non-accruing dividends only when and if declared by the Board of Directors out of funds legally available for that purpose in an amount equal to: $0.10 per share of Series A preferred stock; $0.27 per share of Series B preferred stock; $0.35 per share of Series C preferred stock; $0.60 per share of Series D preferred stock; $0.80 per share of Series E-1 preferred stock; and $1.20 per share of Series E-2 preferred stock (in each case, subject to stock splits, subdivisions, combinations, consolidations and the like with respect to such shares). No dividends could be declared on any series of preferred stock unless dividends were declared on all such preferred stock. After payments of dividends to the holders of preferred stock, dividends may have been declared and distributed among all holders of common stock, provided that no dividend was declared or distributed among the holders of common stock at a greater rate than that at which dividends were paid to the holders of preferred stock (based on the number of shares of common stock into which such preferred stock was convertible on the date the dividend is declared).

Voting rights. The holders of preferred stock were entitled to the number of votes equal to the number of shares of common stock issuable upon conversion of the preferred stock held by such holder, and except as otherwise provided by law or the Restated Certificate of Incorporation, the holders of preferred stock and of common stock voted together on all matters.

Protective provisions. The votes of the holders of a majority of the outstanding shares of each series of preferred stock, voting as a separate class, were required for the approval of certain events relating to (1) authorization or issuance of additional preferred stock having superior preferences or priorities as to dividends, redemption rights, liquidation preferences, conversion rights or voting rights of the given series of preferred stock, and (2) amendments, restatements, modifications or waivers to the Company s certificate of incorporation or bylaws in a manner that was materially adverse to the given series of preferred stock.

Additionally, the votes of the holders of a majority of the outstanding shares of preferred stock, voting together as a single class, were required for the approval of certain events relating to the liquidation, dissolution, or winding-up of the Company, certain redemptions or repurchases of the Company s common stock, and the disposition of the securities of any subsidiary (other than to the Company), any authorization, execution, amendment or termination of any material contract, agreement or other arrangement between the Company and any member of the Company s board of directors, any executive officer or any holder of 10% of the Company s outstanding capital stock, any increase in the number of shares reserved under any equity incentive plan adopted by the Company, and any change in the Company s principal business focus to a field of business other than medical devices.

Redemption. None of the preferred stock was redeemable.

Liquidation, dissolution, or winding-up. In the event of any liquidation or winding up of the Company, the holders of Series E-1 preferred stock, Series E-2 preferred stock and Series D preferred stock were entitled to receive, pari passu and in preference to the holders of the Company s Series C preferred stock, Series B preferred stock, Series A preferred stock and common stock, an amount equal to declared but unpaid dividends on each share of such preferred stock, plus $8.00 per share of Series E-1 preferred stock, $12.00 per share of Series E-2 preferred stock and $6.00 per share of Series D preferred stock. After such payments, the holders of Series C preferred stock were entitled to receive, in preference to the holders of Series B preferred stock, Series A preferred stock and common stock, an amount equal to declared but unpaid dividends on a share of Series C preferred stock plus $3.50 per share.

After such payments, the holders of Series B preferred stock were entitled to receive, in preference to the holders of Series A preferred stock and common stock, an amount equal to declared but unpaid dividends on a share of Series B preferred stock plus $2.69 per share. After such payments, the holders of Series A preferred stock were entitled to receive, in preference to the holders of common stock, an amount equal to declared but unpaid dividends on a share of Series A preferred stock plus $1.00 per share.

After the payments set forth above, proceeds were shared pro rata by the holders of common stock, Series C preferred stock, Series B preferred stock and Series A preferred stock (on an as-converted basis) until such time as the holders of each such series of preferred stock received a total distribution (including the initial preference) of two times their respective original purchase prices. All remaining proceeds thereafter shall be shared pro rata by the holders of common stock. A consolidation or merger of the Company or sale of all or substantially all of its assets or of a majority of its capital stock were deemed to be a liquidation or winding up for purposes of the liquidation preference.

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Right of first refusal. For subsequent issuances of equity securities of the Company (excluding certain specified issuances), the Company granted to certain investors holding at least 300,000 shares of preferred stock (or common stock issued upon conversion of preferred stock) and certain other investors (each a Major Investor) the right to purchase up to their pro rata share of the new securities. Also, had any Major Investor chosen not to purchase its full pro rata share, certain other Major Investors had the right to purchase a portion of the remaining shares.

Demand registration rights

Beginning six months after the closing of the Company s IPO, subject to specified limitations set forth in a registration rights agreement, at any time, the holders of at least 25% of the then outstanding registrable shares may at any time demand in writing that the Company register all or a portion of the registrable shares under the Securities Act on a Form other than Form S-3 for an offering of at least 20% of the then outstanding registrable shares or a lesser percentage of the then outstanding registrable shares provided that it is reasonably anticipated the aggregate offering price would exceed $20 million. The Company is not obligated to file a registration statement pursuant to these rights on more than two occasions.

In addition, after such time as the Company is eligible to use Form S-3, subject to specified limitations set forth in the registration rights agreement, the holders of at least 25% of the then outstanding registrable shares may at any time demand in writing that the Company register all or a portion of the registrable shares under the Securities Act on Form S-3 for an offering of at least 25% of the then outstanding registrable shares having an anticipated aggregate offering price to the public, net of selling expenses, of at least $5 million (a Resale Registration Statement). The Company is not obligated to effect a registration pursuant to a Resale Registration Statement on more than one occasion.

Incidental registration rights

If, at any time after the IPO the Company proposes to file a registration statement to register any of its common stock under the Securities Act in connection with a public offering of such common stock, other than pursuant to certain specified registrations, the holders of registrable shares are entitled to notice of registration and, subject to specified exceptions, including market conditions, the Company will be required, upon the holder s request, to register their then held registrable shares.

Warrants

The Company also issued warrants to certain investors and consultants to purchase shares of the Company s preferred stock and common stock. Based on the Company s assessment of the warrants granted in 2013 and 2014 relative to ASC 480, *Distinguishing Liabilities from Equity*, the warrants are classified as equity. No new warrants were issued in the nine months ended September 30, 2015. According to ASC 480, an entity shall classify as a liability any financial instrument, other than an outstanding share, that, at inception, both a) embodies an obligation to repurchase the issuer s equity shares, or is indexed to such obligation and b) requires or may require the issuer to settle the obligation by transferring assets. The warrants do not contain any provision that requires the Company to repurchase the shares and are not indexed to such an obligation. The warrants also do not require the Company to settle by transferring assets.

All warrants were exercisable immediately upon issuance. Upon the conversion of the Company s preferred stock into common stock in connection with the closing of the Company s IPO, all outstanding warrants to purchase preferred stock instead became warrants to purchase shares of common stock at a ratio of one share of common stock for every two shares of preferred stock.

The fair value of warrants at date of grant was estimated using the Black-Scholes option pricing model, based on the following assumptions:

	Year Ended December 31, 2014
Risk-free interest rate	0.91%-1.71%
Expected term (in years)	2.50-5.00
Dividend yield	0.00%
Expected volatility	50.00%-55.00%

Series C preferred stock warrants

The Company issued warrants to certain investors to purchase up to 594,774 shares of Series C preferred stock at an exercise price range of $0.01 to $3.50 per share of which warrants to purchase 0 shares were outstanding as of September 30, 2015 and

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285,714 shares were outstanding as of December 31, 2014. During the nine months ended September 30, 2015, warrants to purchase 285,714 shares of Series C preferred stock converted to warrants to purchase 142,857 shares of Common stock.

Series D preferred stock warrants

The Company has issued warrants to certain investors and consultants to purchase up to 1,672,529 shares of Series D preferred stock at an exercise price of $6.00 per share, of which warrants to purchase 0 shares of Series D preferred stock were outstanding as September 30, 2015 and 1,246,367 shares of Series D preferred stock were outstanding at December 31, 2014.

Summary of Series D preferred stock warrant activity is as follows:

	Number of Warrants	Weighted Average Exercise Price Per Share (1)	Number of Warrants Exercisable	Weighted Average Price Per Share	Fair Value
Outstanding December 31, 2014	1,246,367	$ 6.00	1,246,367	$ 6.00	$
Granted					
Exercised	(321,854)	6.00	(321,854)	6.00	
Cancelled/expired	(81,848)	6.00	(81,848)	6.00	
Converted to common warrant	(842,665)	6.00	(842,665)	6.00	
Outstanding September 30, 2015 (unaudited)		$		$	$

Series E-1 and E-2 preferred stock warrants

The Company has issued warrants to certain equity investors and consultants to purchase up to 515,866 shares of Series E-1 preferred stock at an exercise price of $8.00 per share, of which warrants to purchase 0 shares of Series E-1 preferred stock were outstanding as of September 30, 2015 and 515,866 shares of Series E-1 preferred stock were outstanding as of December 31, 2014. The Company has issued warrants to certain investors and consultants to purchase up to 403,936 shares of Series E-2 preferred stock at an exercise price of $8.00 per share, of which warrants to purchase 0 shares of Series E-2 preferred stock were outstanding as of September 30, 2015 and 403,936 shares of Series E-2 preferred stock were outstanding as of December 31, 2014.

Summary of Series E-1 preferred stock warrant activity is as follows:

	Number of Warrants	Weighted Average Exercise Price	Number of Warrants Exercisable	Weighted Average Price Per Share	Fair Value

		Per Share				
Outstanding December 31, 2014	515,866	$ 8.00	515,866	$ 8.00	$	
Granted						
Exercised	(300,059)	8.00	(300,059)	8.00		
Cancelled/expired	(215,807)	8.00	(215,807)	8.00		
Outstanding September 30, 2015 (unaudited)		$		$	$	

Summary of Series E-2 preferred stock warrant activity is as follows:

	Number of Warrants	Weighted Average Exercise Price Per Share	Number of Warrants Exercisable	Weighted Average Price Per Share	Fair Value
Outstanding December 31, 2014	403,936	$ 8.00	403,936	$ 8.00	$
Granted					
Exercised	(200,996)	8.00	(200,996)	8.00	
Cancelled/expired	(202,940)	8.00	(202,940)	8.00	
Outstanding September 30, 2015 (unaudited)		$		$	$

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Common stock warrants

The Company also issued warrants to certain investors and consultants to purchase 1,138,424 shares of common stock at an exercise price range of $0.02 to $9.00 per share. Additionally, certain warrants to purchase shares of preferred stock were converted to 564,188 warrants to purchase 564,188 shares of common stock. Warrants to purchase 764,334 shares of common stock were outstanding as of September 30, 2015 and 204,312 shares of common stock were outstanding as of December 31, 2014.

Summary of common stock warrant activity is as follows:

	Number of Warrants	Weighted Average Exercise Price Per Share	Number of Warrants Exercisable	Weighted Average Price Per Share	Fair Value
Outstanding December 31, 2014	204,312	$ 8.90	204,312	$ 8.90	$
Granted					
Exercised	(4,166)	4.32	(4,166)	4.32	
Cancelled/expired					
Converted from preferred warrant	564,188	10.73	564,188	10.73	
Outstanding September 30, 2015 (unaudited)	764,334	$ 10.28	764,334	$ 10.28	$

At September 30, 2015 and December 31, 2014, the range of warrant prices per share for shares under warrants and the weighted average contractual life is as follows:

2015	Number of Warrants	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life	Number of Warrants Exercisable	Weighted Average Price Per Share
Common Stock	764,334	$ 10.28	1.71	764,334	$ 10.28

2014	Number of Warrants	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life	Number of Warrants Exercisable	Weighted Average Price Per Share
Series C	285,714	$ 3.50	2.55	285,714	$ 3.50
Series D	1,246,367	$ 6.00(1)	2.84	1,246,367	$ 6.00
Series E-1	515,866	$ 8.00	4.95	515,866	$ 8.00
Series E-2	403,936	$ 8.00	6.46	403,936	$ 8.00
Common Stock	204,312	$ 8.90	3.26	204,312	$ 8.90

(1) This weighted average exercise price does not give effect to the exchange of warrants to purchase shares of Series D preferred stock for shares of common stock for no additional consideration in connection with the IPO. See Note A Organization and Basis of Presentation.

Stock option plans

In June 2004, the Company authorized the adoption of the 2004 Stock Option and Incentive Plan (the 2004 Plan). Under the 2004 Plan, options were granted to persons who were, at the time of grant, employees, officers, or directors of, or consultants or advisors to, the Company. The 2004 Plan provided for the granting of non-statutory options, incentive options, stock bonuses, and rights to acquire restricted stock.

The option price at the date of grant was determined by the Board of Directors and, in the case of incentive options, could not be less than the fair market value of the common stock at the date of grant, as determined by the Board of Directors. Options granted under the 2004 Plan generally vest over a period of four years and are set to expire 10 years from the date of grant. In February 2011, the Company terminated the 2004 Plan and all options outstanding under it were transferred to the 2011 Stock Option/Stock Issuance Plan (the 2011 Plan).

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In February 2011, the Company authorized the adoption of the 2011 Plan. The 2011 Plan is divided into two separate equity programs, Option Grant Program and Stock Issuance Program. Per the 2011 Plan, options can be granted to persons who are, at the time, employees, officers, or directors of, or consultants or advisors to, the Company. The 2011 Plan provides for the granting of non-statutory options, incentive options and common stock. The price at the date of grant is determined by the Board of Directors and, in the case of incentive options and common stock, cannot be less than the fair market value of the common stock at the date of grant, as determined by the Board of Directors. Options granted under the 2011 Plan generally vest over a period of four years and expire 10 years from the date of grant.

In June 2015, the Company terminated the 2011 Plan and all options outstanding under it were transferred to the 2015 Stock Incentive Plan (the 2015 Plan). The Company had reserved 6,630,242 shares of common stock for issuance under the 2011 Plan including shares previously reserved for under the 2004 Plan, of which 259,403 were still available for grant and transferred to the 2015 Plan.

The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares of our common stock that will be reserved for issuance under the 2015 Plan is the sum of: (1) 2,000,000; plus (2) the number of shares equal to the sum of the number of shares of our common stock then available for issuance under the 2011 Plan and the number of shares of our common stock subject to outstanding awards under the 2011 Plan or under the 2004 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2016 and continuing until, and including, the fiscal year ending December 31, 2025, equal to the least of (a) 3,000,000 shares of our common stock, (b) 3% of the number of shares of our common stock outstanding on the first day of such fiscal year and (c) an amount determined by the Board. Our employees, officers, directors, consultants and advisors will be eligible to receive awards under the 2015 Plan. Incentive stock options, however, may only be granted to our employees. At September 30, 2015, the Company had reserved 2,296,291 shares of common stock for issuance under the 2015 Plan, including shares previously reserved for under the 2004 and 2011 Plans. As of September 30, 2015, 2,247,875 shares of common stock were available for future issuance under the 2015 Plan.

Activity under all stock option plans is as follows:

	Number of Options		Weighted Average Exercise Price per Share
Outstanding December 31, 2014	5,355,567	$	4.87
Granted	400,586		12.14
Exercised	(149,918)		3.75
Expired	(30,696)		5.97
Cancelled/Forfeited	(49,889)		9.36
Outstanding September 30, 2015	5,525,650	$	5.38
Total vested and exercisable	4,346,052		

In 2015, 14,666 shares of restricted common stock awards were granted from the 2015 Plan at a price per share of $15.00. No restricted stock awards under the 2015 Plan were vested as of September 30, 2015.

Stock-based compensation

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options. The determination of the fair value of stock-based payment awards on the date of grant using a pricing model is affected by the value of the Company s common stock as well as assumptions regarding a number of complex and subjective variables. The valuation of the Company s common stock prior to the IPO was performed with the assistance of an independent third-party valuation firm using a methodology that includes various inputs including the Company s historical and projected financial results, peer company public data and market metrics, such as risk-free interest and discount rates. As the valuations included unobservable inputs that were primarily based on the Company s own assumptions, the inputs were considered level 3 inputs within the fair value hierarchy.

The weighted average fair value of options granted was $10.96 per share for the three months ended September 30, 2015, and $5.48 for the nine months ended September 30, 2015.

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The fair value of options at date of grant was estimated using the Black-Scholes option pricing model, based on the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Risk-free interest rate	1.77%	1.66% - 2.29%	1.37% - 1.77%	1.66% - 2.29%
Expected term (in years)	6.25	5.00 - 7.25	5.47 - 6.45	5.00 - 7.25
Dividend yield	0.00%	0.00%	0.00%	0.00%
Expected volatility	49.00%	50.00%	49.00% - 50.00%	50.00%

Risk-free interest rate. The risk-free interest rate is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

Expected term. The expected term of stock options represents the period the stock options are expected to remain outstanding and is based on the SEC Shortcut Approach as defined in *Share-Based Payment* (SAB 107) ASC 718-10-S99, *Compensation Stock Compensation Overall SEC Materials*, which is the midpoint between the vesting date and the end of the contractual term. With certain stock option grants, the exercise price may exceed the fair value of the common stock. In these instances, the Company adjusts the expected term accordingly.

Dividend yield. The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and, therefore, used an expected dividend yield of zero in the valuation model.

Expected volatility. Expected volatility measures the amount that a stock price has fluctuated or is expected to fluctuate during a period. The Company does not have sufficient history of market prices of its common stock as it is a newly public company. Therefore, the Company estimates volatility using historical volatilities of similar public entities.

Forfeitures. The Company uses historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. If the Company s actual forfeiture rate is materially different from its estimate, the stock-based compensation expense could be significantly different from what the Company has recorded in the current period.

Employee stock-based compensation expense recognized was $0.7 million and $0.9 million for the three months ended September 30, 2015 and 2014, respectively, and $2.6 million and $1.8 million for the nine months ended September 30, 2015 and 2014, respectively. Stock-based compensation expense was calculated based on awards ultimately expected to vest. To date, the amount of stock-based compensation capitalized as part of inventory was not material.

The following is a summary of stock-based compensation expense (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Cost of revenues	$ 41	$ 45	$ 194	$ 127
Sales and marketing	151	220	541	437
Research and development	161	194	574	450
General and administrative	395	437	1,285	782
	$ 748	$ 896	$ 2,594	$ 1,796

At September 30, 2015, the Company had $4.7 million of total unrecognized compensation expense that will be recognized over a weighted average period of 2.33 years.

Note N Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company recorded a provision for income taxes of $8,100 and $9,000 for the three months ended September 30, 2015 and 2014, respectively, and $29,300, and $28,900 for the nine months ended September 30, 2015 and 2014, respectively.

As of September 30, 2015 and December 31, 2014, the Company had reserves for uncertain tax positions of $3.4 million and $2.5 million, respectively, of which $3.3 million and $2.4 million were netted against the Company s net operating losses.

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The Company does not expect that its unrecognized tax benefits will materially increase within the next twelve months.

The Company recognizes interest and penalties related to income taxes as a component of income tax expense. As of September 30, 2015 and December 31, 2014, $4,800 and $1,700 of interest and penalties have been accrued, respectively.

The Company continues to maintain a valuation allowance against certain deferred tax assets where it is more likely than not that the deferred tax asset will not be realized because of its extended history of annual losses. Such deferred tax assets principally relate to tax net operating losses and credit carryforwards in certain jurisdictions for which sufficient taxable income for the utilization cannot be projected at this time, which may result in net operating losses or credits or both potentially expiring without being utilized due to shorter carryforward periods. Management assesses the need for the valuation allowance on a quarterly basis. In assessing the need for a valuation allowance, the Company considers all positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, and past financial performance. If and when management determines the valuation allowance should be released, the adjustment would result in a tax benefit in the Consolidated Statements of Operations and may include a portion to be accounted for through Additional paid-in capital, a component of Stockholders Equity. The amount of the tax benefit to be recorded in a particular quarter could be material. Management does not believe it is more likely than not that the Company s net federal deferred tax assets as of September 30, 2015 will be realized based upon its assessment of all available evidence, both positive and negative.

Note O Segment and Geographic Data

The Company operates as one reportable segment as described in Note B to the Consolidated Financial Statements. The countries in which the Company has local revenue generating operations have been combined into the following geographic areas: the United States (including Puerto Rico), and the rest of the word, which consists of Europe predominately (including Germany, Switzerland and the United Kingdom) and other foreign countries. Sales are attributable to a geographic area based upon the customer s country of domicile. Net property, plant and equipment are based upon physical location of the assets.

Geographic information consists of the follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Product Revenue				
United States	$ 10,493	$ 8,804	$ 32,676	$ 23,783
Rest of World	2,997	3,198	11,277	10,192
	$ 13,490	$ 12,002	$ 43,953	$ 33,975

	September 30, 2015	December 31, 2014
Property and equipment, net		
United States	$ 10,525	$ 8,540
Rest of World	130	156

$	10,655	$	8,696

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our final prospectus, dated June 30, 2015, for our initial public offering and filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on July 1, 2015, which we refer to as the Prospectus . Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the Risk Factors sections of the Prospectus and in Part II Item 1A of this report our actual results could differ materially from the results described, in or implied, by these forward-looking statements.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words anticipate, believe, continue, could, estimate, expect, intend, may, might, plan, potential, predict, project, would or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our estimates regarding the potential market opportunity and timing of estimated commercialization for our current and future products, including our iTotal CR, our iTotal PS and, if we receive required marketing clearances or approvals, our iTotal Hip;

- our expectations regarding our sales, expenses, gross margins and other results of operations;

- our strategies for growth and sources of new sales;

- maintaining and expanding our customer base and our relationships with our independent sales representatives and distributors;

- our current and future products and plans to promote them;

- anticipated trends and challenges in our business and in the markets in which we operate;

- the implementation of our business model, strategic plans for our business, products, product candidates and technology;

- the future availability of raw materials used to manufacture, and finished components for, our products from third-party suppliers, including single source suppliers;

- product liability claims;

- the impact of our voluntary recall in August 2015;

- our ability to retain and hire necessary employees and to staff our operations appropriately;

- our ability to compete in our industry and with innovations by our competitors;

- potential reductions in reimbursement levels by third-party payors and cost containment efforts of accountable care organizations;

- our ability to protect proprietary technology and other intellectual property and potential claims against us for infringement of the intellectual property rights of third parties;

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- potential challenges relating to changes in and compliance with governmental laws and regulations affecting our U.S. and international businesses, including regulations of the U.S. Food and Drug Administration and foreign government regulators, such as more stringent requirements for regulatory clearance of our products;

- the impact of federal legislation to reform the United States healthcare system and the 2.3 percent medical device excise tax;

- the anticipated adequacy of our capital resources to meet the needs of our business; and

- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q and in the Risk Factors sections of this Quarterly Report on Form 10-Q and the Prospectus, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q and our other filings with the SEC completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Overview

We are a medical technology company that uses our proprietary iFit Image-to-Implant technology platform to develop, manufacture and sell joint replacement implants that are individually sized and shaped, which we refer to as customized, to fit each patient s unique anatomy. The worldwide market for joint replacement products is approximately $15 billion annually and growing, and we believe our iFit technology platform is applicable to all major joints in this market. We believe we are the only company offering a broad line of customized knee implants designed to restore the natural shape of a patient s knee. We have sold a total of more than 30,000 knee implants in the United States and Europe. In recent clinical studies, iTotal CR, our cruciate-retaining total knee replacement implant and best-selling product, demonstrated superior clinical outcomes, including better function and greater patient satisfaction compared to traditional, off-the-shelf implants. We recently initiated the limited launch of iTotal PS, our posterior-stabilized total knee replacement implant which addresses the largest segment of the knee replacement market. We are also in development of the iTotal Hip, our first customized hip replacement implant.

Our iFit technology platform comprises three key elements:

•*iFit Design*, our proprietary algorithms and computer software that we use to design customized implants and associated single-use patient-specific instrumentation, which we refer to as iJigs, based on computed tomography, or CT scans of the patient and to prepare a surgical plan customized for the patient that we call iView.

•*iFit Printing*, a three-dimensional, or 3D, printing technology that we use to manufacture iJigs and are in the process of extending to manufacture certain components of our customized knee replacement implants.

•*iFit Just-in-Time Delivery*, our just-in-time manufacturing and delivery capabilities.

We believe our iFit technology platform enables a scalable business model that greatly lowers our inventory requirements, reduces the amount of working capital required to support our operations and allows us to launch new products and product improvements more rapidly, as compared to manufacturers of traditional, off-the-shelf implants.

All of our knee replacement products have been cleared by the FDA under the premarket notification process of Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, and have received certification to CE Mark. We market our products to orthopedic surgeons, hospitals and other medical facilities and patients. We have 98 employees engaged in the sales and marketing of our products in the United States, Germany and the United Kingdom. We use independent sales representatives and distributors to complement our own sales and marketing efforts in these and other markets.

We were incorporated in Delaware and commenced operations in 2004. We introduced our iUni and iDuo partial knee replacement products in 2007, our iTotal CR in 2011 and our iTotal PS on a limited basis in 2015. We expect to initiate the broad commercial launch of our iTotal PS in March 2016.

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Components of our results of operations

The following is a description of factors that may influence our results of operations, including significant trends and challenges that we believe are important to an understanding of our business and results of operations.

Revenue

Our product revenue is generated from sales to hospitals and other medical facilities that are served through a direct sales force, independent sales representatives and distributors in the United States, the United Kingdom, Austria, Germany, Ireland, Switzerland, Hong Kong and Singapore. In order for surgeons to use our products, the medical facilities where these surgeons treat patients typically require us to enter into purchasing contracts. The process of negotiating a purchasing contract can be lengthy and time-consuming, require extensive management time and may not be successful.

Revenue from sales of our products fluctuates principally based on the selling price of the joint replacement product, as the sales price of our products varies among hospitals and other medical facilities. In addition, our product revenue may fluctuate based on the product sales mix and mix of sales by geography. Our product revenue from international sales can be significantly impacted by fluctuations in foreign currency exchange rates, as our sales are denominated in the local currency in the countries in which we sell our products. We expect our product revenue to fluctuate from quarter-to-quarter due to a variety of factors, including seasonality, as we have historically experienced lower sales in the summer months and around year-end, the timing of the introduction of our new products, if any, and the impact of the buying patterns and implant volumes of medical facilities.

In April 2015, we entered into a fully paid up, worldwide license agreement with Wright Medical Group, Inc., or Wright Group, and its wholly owned subsidiary Wright Medical Technology, Inc., or Wright Technology and collectively with Wright Group, Wright Medical. Under the terms of this license agreement, we granted a perpetual, irrevocable, non-exclusive license to Wright Medical to use patient-specific instrument technology covered by our patents and patent applications with off-the-shelf implants in the foot and ankle. This license does not extend to patient-specific implants. This license agreement provided for a single lump-sum payment by Wright Medical to us of mid-single digit millions of dollars upon entering into the license agreement, which has been paid. This license agreement will expire upon the expiration of the last to expire of our patents and patent applications licensed to Wright Medical, which currently is expected to occur in 2031.

In April 2015, we entered into a worldwide license agreement with MicroPort Orthopedics Inc., or MicroPort, a wholly owned subsidiary of MicroPort Scientific Corporation. Under the terms of this license agreement, we granted a perpetual, irrevocable, non-exclusive license to MicroPort to use patient-specific instrument technology covered by our patents and patent applications with off-the-shelf implants in the knee. This license does not extend to patient-specific implants. This license agreement provides for the payment to us of a fixed royalty at a high single to low double digit percentage of net sales on patient-specific instruments and associated implant components in the knee, including MicroPort s Prophecy patient-specific instruments used with its Advance and Evolution implant components. We cannot be certain as to the timing or amount of payment of any royalties under this license agreement. This license agreement also provided for a single lump-sum payment by MicroPort to us of low-single digit millions of dollars upon entering into the license agreement, which has been paid. This license agreement will expire upon the expiration of the last to expire of our patents and patent applications licensed to MicroPort, which currently is expected to occur in 2029.

We have accounted for the agreements with Wright Medical and MicroPort under ASC 605-25, Multiple-Element Arrangements and Staff Accounting Bulletin No. 104, Revenue Recognition (ASC 605). In accordance with ASC 605, we were required to identify and account for each of the separate units of accounting. We identified the relative selling price for each and then allocated the total consideration based on their relative values. In connection with these agreements, in April 2015, we recognized in aggregate (i) back-owed royalties of $3.4 million as royalty revenue and (ii) the value attributable to the settlements of $0.2 million as other income. Additionally, we recognized an initial $5.1 million in aggregate as deferred royalty revenue, which is recognized as royalty revenue ratably through 2031. See Note I Deferred Revenue to the financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. The on-going royalty from MicroPort is recognized as royalty revenue upon receipt of payment.

On August 31, 2015, we announced a voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems. We initiated the voluntary recall in response to three complaints of excess moisture on patient-specific instrumentation. Based on our investigation into the cause of the excess moisture, we believe that the affected instrumentation underwent the commonly used ethylene oxide sterilization process in the presence of excess water and, as a result, contained small amounts of ethylene glycol residue. Ethylene glycol residue may form when ethylene oxide comes into contact with water. We temporarily suspended our use of the ethylene oxide sterilization process on August 28, 2015. We completed final testing, implemented corrective actions, and resumed normal production in October 2015. In September 2015, as a result of the voluntary recall, sales

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were negatively impacted by the recalled products that were shipped and not used and the lower production capacity over the period of investigation and resolution.

Cost of revenue

We produce all of our computer aided designs (CAD) in-house and use them to direct all of our product manufacturing efforts. Until July 2015, we manufactured all of our patient-specific instruments, or iJigs, in our facilities in Burlington and Wilmington, Massachusetts. Beginning in July 2015, we manufacture all of our iJigs in our Wilmington facility. We also make in our facilities the majority of the tibial components used in our implants. We outsource the production of the remainder of the tibial components and the manufacture of femoral and other implant components to third-party suppliers. Our suppliers make our customized implant components using the CAD designs we supply. Cost of revenue consists primarily of costs of raw materials, manufacturing personnel, manufacturing supplies, inbound freight and manufacturing overhead and depreciation expense.

We calculate gross margin as revenue less cost of revenue divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, including primarily volume of units produced, mix of product components manufactured by us versus sourced from third parties, our average selling price, the geographic mix of sales, royalty revenue and product sales mix.

We expect our gross margin from the sale of our products, which excludes royalty revenue, to expand over time to the extent we are successful in reducing our manufacturing costs per unit and increasing our manufacturing efficiency as sales volume increases. We believe that areas of opportunity to expand our gross margins in the future, if and as the volume of our product sales increases, include the following:

• absorbing overhead costs across a larger volume of product sales;

• obtaining more favorable pricing for the materials used in the manufacture of our products;

• increasing the proportion of certain components of our products that we manufacture in-house, which we believe we can manufacture at a lower unit cost than vendors we currently use;

• applying our 3D printing technology to select metal components of our products, which we believe can lower our unit costs compared to our current manufacturing methods;

• developing new versions of our software used in the design of our customized joint replacement implants, which we believe will reduce costs associated with the design process; and

• obtaining more favorable pricing of certain components of our products manufactured for us by third parties.

We also plan to explore other opportunities to reduce our manufacturing costs. However, these and the above opportunities may not be realized. In addition, our gross margin may fluctuate from period to period.

In connection with the voluntary recall announced in August 2015, we incurred incremental charges amounting to approximately $1.1 million related to a write-down of recalled inventory and estimated surgery cancellations.

Operating expenses

Our operating expenses consists of sales and marketing, research and development and general and administrative expenses. Personnel costs are the most significant component of operating expenses and consists of salaries, benefits, stock-based compensation and sales commissions.

Sales and marketing. Sales and marketing expense consists primarily of personnel costs, including salary, employee benefits and stock-based compensation for personnel employed in sales, marketing, customer service, medical education and training, as well as investments in surgeon training programs, industry events and other promotional activities. In addition, our sales and marketing expense includes sales commissions and bonuses, generally based on a percentage of sales, to our sales managers, direct sales representatives and independent sales representatives. Recruiting, training and retaining productive sales representatives and educating surgeons about the benefits of our products are required to generate and grow revenue. We expect sales and marketing expense to significantly increase as we build up our sales and support personnel and expand our marketing efforts. Our sales and marketing expense may fluctuate from period to period due to the seasonality of our revenue and the timing and extent of our expenses.

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Research and development. Research and development expense consists primarily of personnel costs, including salary, employee benefits and stock-based compensation for personnel employed in research and development, regulatory and clinical areas. Research and development expense also includes costs associated with product design, product refinement and improvement efforts before and after receipt of regulatory clearance, development prototypes, testing, clinical study programs and regulatory activities, contractors and consultants, and equipment and software to support our development. As our revenue increases, we will also incur additional expenses for revenue share payments to our past and present scientific advisory board members, including our Chief Executive Officer. We expect research and development expense to increase in absolute dollars as we develop new products to expand our product pipeline, add research and development personnel and conduct clinical activities.

General and administrative. General and administrative expense consists primarily of personnel costs, including salary, employee benefits and stock-based compensation for our administrative personnel that support our general operations, including executive management, general legal and intellectual property, finance and accounting, information technology and human resources personnel. General and administrative expense also includes outside legal costs associated with intellectual property and general legal matters, financial audit fees, insurance, fees for other consulting services, depreciation expense, freight, medical device tax and facilities expense.

We expect our general and administrative expense will increase in absolute dollars as we increase our headcount and expand our infrastructure to support growth in our business and our operations as a public company. We anticipate increased expenses associated with being a public company will include increases in audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs. As our revenue increases we also will incur additional expenses for freight and medical device tax. Our general and administrative expense may fluctuate from period to period due to the timing and extent of the expenses.

Other income (expense), net

Other income (expense), net consists primarily of interest expense and amortization of debt discount associated with our term loans and realized gains (losses) from foreign currency transactions. The effect of exchange rates on our foreign currency-denominated asset and liability balances are recorded in other income (expense) and are recorded as foreign currency translation adjustments in the consolidated statements of comprehensive loss.

Income tax provision

Income tax provision consists primarily of a provision for income taxes in foreign jurisdictions in which we conduct business. We maintain a full valuation allowance for deferred tax assets including net operating loss carryforwards and research and development credits and other tax credits.

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Consolidated results of operations

Comparison of the three months ended September 30, 2015 and 2014

The following table sets forth our results of operations expressed as dollar amounts, percentage of total revenue and quarter-to-quarter change (in thousands):

	2015		2014		2015 vs 2014	
Three months ended September 30,	**Amount**	**As a% of Total Revenue**	**Amount**	**As a % of Total Revenue**	**$ Change**	**% Change**
Revenue						
Product revenue	$ 13,490	97%	$ 12,002	100%	$ 1,488	12%
Royalty	404	3			404	100
Total revenue	13,894	100	12,002	100	1,892	16
Cost of revenue	10,340	74	7,351	61	2,989	41
Gross profit	3,554	26	4,651	39	(1,097)	(24)
Operating expenses:						
Sales and marketing	10,225	74	7,083	59	3,142	44
Research and development	3,885	28	3,969	33	(84)	(2)
General and administrative	5,656	41	3,927	33	1,729	44
Total operating expenses	19,766	142	14,979	125	4,787	32
Loss from operations	(16,212)	(117)	(10,328)	(86)	(5,884)	(57)
Total other expenses	(887)	(6)	(59)	(1)	(828)	(1,403)
Loss before income taxes	(17,099)	(123)	(10,387)	(87)	(6,712)	(65)
Income tax provision	8		9		(1)	(11)
Net loss	$ (17,107)	(123)%	$ (10,396)	(87)%	$ (6,711)	(65)%

Revenue. Product revenue was $13.5 million for the three months ended September 30, 2015 compared to $12.0 million for the three months ended September 30, 2014, an increase of $1.5 million or 12%, due principally to increased sales of our first primary total knee product, iTotal CR, as well as the addition on a limited basis of our iTotal PS product line.

The following table sets forth, for the periods indicated, our product revenue by geography expressed as U.S. dollar amounts, percentage of product revenue and year-over-year change (in thousands):

	2015		2014		2015 vs 2014	
Three months ended September 30,	**Amount**	**As a % of Product Revenue**	**Amount**	**As a % of Product Revenue**	**$ Change**	**% Change**
United States	$ 10,493	78%	$ 8,804	73%	$ 1,689	19%

Rest of world		2,997	22	3,198	27	(201)	(6)
Product revenue	$	13,490	100% $	12,002	100% $	1,488	12%

Product revenue in the United States is generated through our direct sales force and independent sales representatives. Product revenue outside the United States is generated through our direct sales force and distributors. The percentage of product revenue generated in the United States was 78% for the three months ended September 30, 2015 compared to 73% for the three months ended September 30, 2014. We believe the lower level of rest of world product revenue as a percentage of product revenue in the three months ended September 30, 2015 was due to the decline in foreign currency exchange rates for sales made in Germany and the United Kingdom and the increase in sales of the iTotal PS.

In April 2015, we entered into a fully paid up, worldwide license agreement with Wright Medical for a single lump-sum payment by Wright Medical to us upon entering into the agreement. At this same time we also entered into a worldwide license agreement with MicroPort for a single lump-sum payment by MicroPort to us upon entering into the license agreement. Royalty revenue related to these agreements was $0.4 million for the three months ended September 30, 2015.

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Cost of revenue, gross profit and gross margin. Cost of revenue was $10.4 million for the three months ended September 30, 2015 compared to $7.4 million for the three months ended September 30, 2014, an increase of $3.0 million or 41%. The increase was due primarily to an increase in production and personnel costs associated with the planned increase in sales volume which was not achieved due to the recall. Gross profit was $3.6 million for the three months ended September 30, 2015 compared to $4.7 million for the three months ended September 30, 2014, a decrease of $1.1 million or 24%. Gross margin decreased 1300 basis points to 26% for the three months ended September 30, 2015 from 39% for the three months ended September 30, 2014. This decrease in gross margin was primarily caused by the additional production costs and decrease in revenue due to the recall announced in August 2015 and foreign currency exchange rate changes during the three months ended September 30, 2015.

Sales and marketing. Sales and marketing expense was $10.2 million for the three months ended September 30, 2015 compared to $7.1 million for the three months ended September 30, 2014, an increase of $3.1 million or 44%. The increase was due primarily to a $1.7 million increase in personnel costs as a result of our hiring of additional direct sales representatives and sales support and increases in commissions as a result of the increase in sales volume, and a $1.4 million increase in marketing and other expenses.

Research and development. Research and development expense was $3.9 million for the three months ended September 30, 2015 compared to $4.0 million for the three months ended September 30, 2014, a decrease of $0.1 million or 2%. The decrease was due primarily to a $0.3 million decrease in other research expenses which was offset in part by a $0.2 million increase in personnel costs.

General and administrative. General and administrative expense was $5.7 million for the three months ended September 30, 2015 compared to $3.9 million for the three months ended September 30, 2014, an increase of $1.7 million or 44%. The increase was due primarily to a $0.2 million increase in personnel costs, a $0.4 million increase in facilities and office relocation costs, a $0.3 million increase in bank fees related to the prepayment of our term loan, a $0.2 million increase in general and patent legal fees, a $0.2 million increase in corporate director and officers insurance and a $0.4 million increase in various other expenses.

Other expense, net. Other expense, net was $887,000 for the three months ended September 30, 2015 compared to $59,000 for the three months ended September 30, 2014, an increase of $828,000, or 1,403%. The increase was primarily due to the acceleration of the final payment fee of $700,000 related to the prepayment of our term loan and $128,000 in interest expense, which was offset in part by a decrease of $6,000 in miscellaneous income and $46,000 of realized loss on currency conversion.

Income taxes. Income tax provision was $8,000 for the three months ended September 30, 2015 compared to $9,000 for the three months ended September 30, 2014. We continue to generate losses for U.S. federal and state tax purposes and have net operating loss carryforwards creating a deferred tax asset. We maintain a full valuation allowance for

deferred tax assets.

Comparison of the nine months ended September 30, 2015 and 2014

The following table sets forth our results of operations expressed as dollar amounts, percentage of total revenue and year-over-year change (in thousands):

	2015		2014		2015 vs 2014	
Nine months ended September 30,	**Amount**	**As a% of Total Revenue**	**Amount**	**As a% of Total Revenue**	**$ Change**	**% Change**
Revenue						
Product revenue	$ 43,953	92%	$ 33,975	100%	$ 9,978	29%
Royalty	3,863	8			3,863	100
Total revenue	47,816	100	33,975	100	13,841	41
Cost of revenue	30,392	64	21,961	65	8,431	38
Gross profit	17,424	36	12,014	35	5,410	45
Operating expenses:						
Sales and marketing	29,563	62	22,541	66	7,022	31
Research and development	12,218	26	11,163	33	1,055	9
General and administrative	16,790	35	11,775	35	5,015	43
Total operating expenses	58,571	122	45,479	134	13,092	29
Loss from operations	(41,147)	(86)	(33,465)	(98)	(7,682)	(23)
Total other expenses	(1,080)	(2)	(98)	(1)	(982)	(1,002)
Loss before income taxes	(42,227)	(88)	(33,563)	(99)	(8,664)	(26)
Income tax provision	29		29			
Net loss	$ (42,256)	(88)%	$ (33,592)	(99)%	$ (8,664)	(26)%

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Revenue. Product revenue was $44.0 million for the nine months ended September 30, 2015 compared to $34.0 million for the nine months ended September 30, 2014, an increase of $10.0 million or 29%, due principally to increased sales of our first primary total knee product, iTotal CR, as well as the addition on a limited basis of our iTotal PS product line.

The following table sets forth, for the periods indicated, our product revenue by geography expressed as U.S. dollar amounts, percentage of product revenue and year-over-year change (in thousands):

	2015		2014		2015 vs 2014	
Nine months ended September 30,	**Amount**	**As a % of Product Revenue**	**Amount**	**As a % of Product Revenue**	**$ Change**	**% Change**
United States	$ 32,676	74%	$ 23,783	70%	$ 8,893	37%
Rest of world	11,277	26	10,192	30	1,085	11
Product revenue	$ 43,953	100%	$ 33,975	100%	$ 9,978	29%

Product revenue in the United States is generated through our direct sales force and independent sales representatives. Product revenue outside the United States is generated through our direct sales force and distributors. The percentage of product revenue generated in the United States was 74% for the nine months ended September 30, 2015 compared to 70% for the nine months ended September 30, 2014. We believe the lower level of rest of world product revenue as a percentage of product revenue in the nine months ended September 30, 2015 was due to the decline in foreign currency exchange rates for sales made in Germany and the United Kingdom and the increase in sales of iTotal PS in the United States.

In April 2015, we entered into a fully paid up, worldwide license agreement with Wright Medical for a single lump-sum payment by Wright Medical to us upon entering into the agreement. At this same time we also entered into a worldwide license agreement with MicroPort for a single lump-sum payment by MicroPort to us upon entering into the license agreement. Royalty revenue related to these agreements was $3.9 million for the nine months ended September 30, 2015.

Cost of revenue, gross profit and gross margin. Cost of revenue was $30.3 million for the nine months ended September 30, 2015 compared to $21.9 million for the nine months ended September 30, 2014, an increase of $8.4 million or 38%. The increase was due primarily to an increase in production and personnel costs associated with the planned increase in sales volume which was not achieved due to the recall announced in August 2015. Gross profit was $17.4 million for the nine months ended September 30, 2015 compared to $12.0 million for the nine months ended September 30, 2014, an increase of $5.4 million or 45%. Gross margin increased 100 basis points to 36% for the nine months ended September 30, 2015 from 35% for the nine months ended September 30, 2014. This increase in gross margin was driven primarily by the royalty revenue and higher sales volume during the nine months ended September 30, 2015 which was offset in part by the additional product costs, decrease in revenue due to the recall and foreign currency exchange rate changes.

Sales and marketing. Sales and marketing expense was $29.5 million for the nine months ended September 30, 2015 compared to $22.5 million for the nine months ended September 30, 2014, an increase of $7.0 million or 31%. The increase was due primarily to a $5.9 million increase in personnel costs as a result of our hiring of additional direct sales representatives and sales support and increases in commissions as a result of the increase in sales volume, and a $1.1 million increase in marketing and other expenses.

Research and development. Research and development expense was $12.2 million for the nine months ended September 30, 2015 compared to $11.2 million for the nine months ended September 30, 2014, an increase of $1.0 million or 9%. The increase was due primarily to a $0.8 million increase in personnel costs and a $0.7 million increase in revenue share expenses, offset in part by a $0.5 million decrease in other research expenses.

General and administrative. General and administrative expense was $16.8 million for the nine months ended September 30, 2015 compared to $11.8 million for the nine months ended September 30, 2014, an increase of $5.0 million or 43%. The increase was due primarily to a $1.5 million increase in personnel costs, $1.0 million increase in freight, a $0.9 million increase in facilities and office relocation costs, a $0.8 million increase in consulting services expense, a $0.3 million increase in bank fees related to the prepayment of our term loan, a $0.2 million increase in corporate director and officers insurance and a $1.0 million increase in various other expenses, offset in part by a decrease of $0.7 million in general and patent legal fees.

Other expense, net. Other expense, net was $1.1 million for the nine months ended September 30, 2015 compared to $98,000 for the nine months ended September 30, 2014, an increase of $1.0 million, or 1,002%. The increase was primarily due to an increase of $0.5 million in interest expense associated with our long-term debt, an increase of $0.8 million related to the prepayment of our term loan and $71,000 of realized loss on currency conversion, which was offset by $0.2 million in other income related to a gain on the royalty settlement from Wright and MicroPort.

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Income taxes. Income tax provision was $29,000 for the nine months ended September 30, 2015 and 2014. We continue to generate losses for U.S. federal and state tax purposes and have net operating loss carryforwards creating a deferred tax asset. We maintain a full valuation allowance for deferred tax assets.

Liquidity, capital resources and plan of operations

Sources of liquidity and funding requirements

From our inception in June 2004 through the nine months ended September 30, 2015, we have financed our operations through private placements of preferred stock, our IPO, bank debt and convertible debt financings, equipment purchase loans and product revenue beginning in 2007. Our product revenue has continued to grow from year-to-year; however, we have not yet attained profitability and continue to incur operating losses. As of September 30, 2015, we had an accumulated deficit of $310.4 million.

From 2004 through the nine months ended September 30, 2015, we have raised an aggregate of $330 million from the sale of preferred stock and the exercise of preferred stock warrants and common stock warrants and options.

In June 2011, we entered into a $1.4 million secured term loan facility with the Massachusetts Development Financing Agency, referred to as the MDFA facility, to finance equipment purchases, of which $0.52 million was outstanding as of September 30, 2015 and $0.76 million was outstanding as of December 31, 2014. We are scheduled to make monthly interest and principal payments for the MDFA facility through July 2017. For further information regarding this facility, see Note K Debts and Notes Payable $1.4 million term loan Massachusetts Development Finance Agency in the financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

In May 2014, we made the final payment on a $15 million term loan facility with Western Technology Investment under which we originally borrowed $10 million in 2011.

In November 2014, we entered into a senior secured $25 million loan and security agreement with Silicon Valley Bank and Oxford Finance, LLC, referred to as the 2014 Secured Loan Agreement consisting of a revolving line of credit issued by Silicon Valley Bank, or the Revolving Line, of up to $5 million and commitments for two term loans issued jointly by Silicon Valley Bank and Oxford Finance, LLC, or the SVB/Oxford Term Loans, of $10 million each. In November 2014, in connection with our entry into the 2014 Secured Loan Agreement, we drew down the first $10 million term loan, referred to as the SVB/Oxford Term Loan A. In September 2015, we voluntarily prepaid the SVB/Oxford Term Loan A and terminated the Company s right to draw down the SVB/Oxford Term Loans and any security interest in favor of Oxford Finance, LLC. Prior to repaying the term loan, we were eligible to draw down the second $10 million term loan on or prior to November 7, 2015 upon meeting certain conditions. As of September 30, 2015, we did not have any revolving loans outstanding under the Revolving Line, with $5 million available for borrowing, subject to our meeting certain conditions, based on our borrowing base under the Revolving Line. We believe our need for the availability of the second $10 million term loan and loans under the Revolving Line will be reduced significantly due to proceeds from our IPO, which closed on July 7, 2015. For further information regarding this

facility, see Note K Debts and Notes Payable 2014 Secured Loan Agreement in the financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

On July 7, 2015, we closed our initial public offering of our common stock and issued and sold 10,350,000 shares of our common stock, including 1,350,000 shares of common stock issued upon the exercise in full by the underwriters of their over-allotment option, at a public offering price of $15.00 per share, for aggregate offering proceeds of approximately $155 million. We received aggregate net proceeds from the offering of approximately $140 million after deducting underwriting discounts and commissions and offering expenses payable by us. Our common stock began trading on the NASDAQ Global Select Market on July 1, 2015.

We expect to incur substantial expenditures in the foreseeable future in connection with the following:

• expansion of our sales and marketing efforts;

• expansion of our manufacturing capacity;

• funding research, development and clinical activities related to our existing products and product platform, including iFit design software and product support;

• funding research, development and clinical activities related to new products that we may develop, including other joint replacement products;

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• pursuing and maintaining appropriate regulatory clearances and approvals for our existing products and any new products that we may develop;

• servicing our indebtedness under our existing credit facilities; and

• preparing, filing and prosecuting patent applications, and maintaining and enforcing our intellectual property rights and position.

In addition, our general and administrative expense will increase due to the additional operational and reporting costs associated with our expanded operations and being a public company.

We anticipate that our principal sources of funds in the future will be revenue generated from the sales of our products and revenues that we may generate in connection with licensing our intellectual property. Our Revolving Line with SVB is our only committed external source of funds. We will need to generate significant additional revenue to achieve and maintain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. It is also possible that we may allocate significant amounts of capital toward products or technologies for which market demand is lower than anticipated and, as a result, abandon such efforts. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, or if we expend capital on projects that are not successful, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, and we may even have to scale back our operations. Our failure to become and remain profitable could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue to fund our operations.

We may need to engage in additional equity or debt financings to secure additional funds, including the funds required to pay our existing indebtedness at maturity. We may not be able to obtain additional financing on terms favorable to us, or at all. In addition, the negative covenants, pledge of our assets as collateral and negative pledge with respect to our intellectual property under the 2014 Secured Loan Agreement could limit our ability to obtain additional debt financing. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted. The terms of these future equity or debt securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders or involve negative covenants that restrict our ability to take specific actions, such as incurring additional debt or making capital expenditures.

At September 30, 2015, we had cash and cash equivalents of $139.2 million and $0.7 million in restricted cash allocated to lease deposits. Based on our current operating plan, we expect that our existing cash and cash equivalents as of September 30, 2015 and anticipated revenue from operations, including from projected sales of our products, will enable us to fund our operating expenses and capital expenditure requirements and pay our debt service as it becomes due for at least the next 12 months. We have based this expectation on assumptions that may prove to be wrong, such as the revenue that we expect to generate from the sale of our products and the gross profit we expect to generate

from those revenues, and we could use our capital resources sooner than we expect.

Cash flows

The following table sets forth a summary of our cash flows for the periods indicated, as well as the year-over-year change between periods (in thousands):

	Nine Months September 30,			
	2015	**2014**	**$ Change**	**% Change**
Net cash (used in) provided by:				
Operating activities	$ (33,499)	$ (32,226)	$ (1,273)	(4)%
Investing activities	51	(81)	132	163
Financing activities	134,596	19,571	115,025	588
Effect of exchange rate on cash	154	(543)	697	128
Total	$ 101,302	$ (13,279)	$ 114,581	863

Cash used in operating activities. Net cash used in operating activities was $33.5 million for the nine months ended September 30, 2015 and $32.2 million for the nine months ended September 30, 2014, an increase of $1.3 million. These amounts primarily reflect net losses of $42.3 million for the nine months ended September 30, 2015 and $33.6 million for the nine months ended September 30, 2014. The net cash used in operating activities for the nine months ended September 30, 2015 was affected by changes in our operating assets and liabilities, including an increase of $2.0 million in accounts payable and accrued liabilities, an increase in deferred royalty revenue of $5.0 million as well as non-cash stock-based compensation and depreciation totaling

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$1.5 million, a decrease in our accounts receivable of $2.2 million, which were offset in part by an increase in our outstanding prepaid and other assets of $0.6 million and an increase in our inventory of $2.9 million.

Net cash provided by (used in) investing activities. Net cash provided by investing activities was $51,000 for the nine months ended September 30, 2015 and net cash used in investing activities was $81,000 for the nine months ended September 30, 2014, a decrease of $132,000. These amounts primarily reflect a $2.9 million decrease in restricted cash balances offset by an increase of $2.9 million in cash used for purchases of property and equipment. We anticipate that the amount of cash used in investing activities will increase in 2015 as we purchase additional property and equipment to manufacture more components in our own facility.

Net cash provided by financing activities. Net cash provided by financing activities was $134.6 million for the nine months ended September 30, 2015 and $19.6 million for the nine months ended September 30, 2014, an increase of $115.0 million. The increase was due to a $123.1 million increase in net proceeds from the issuance of common and preferred stock, which was offset by an $8.1 million increase in debt payments primarily related to the prepayment of the SVB/Oxford Term Loan A.

Contractual obligations and commitments

During the nine months ended September 30, 2015, there were no material changes to our contractual obligations and commitments described under Management s Discussion and Analysis of Financial Condition and Results of Operations in the Prospectus.

Legal proceedings

In the ordinary course of conducting business, we are subject to litigation, claims and administrative proceedings on a variety of matters. An estimate of the possible loss or range of loss as a result of any of these matters cannot be made; however, management does not believe that these matters, individually or in the aggregate, are material to its financial condition, results of operations or cash flows.

In September 2015, a class action lawsuit was filed against us and certain of our officers on behalf of stockholders who purchased our common stock in connection with the IPO or on the open market between July 1, 2015 and August 28, 2015 alleging that statements made were false and misleading. We believe we have valid defenses to the claims in the lawsuit, will deny liability and intend to defend ourselves vigorously. We are presently unable to predict the outcome of the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit.

In October 2015, a complaint for patent infringement was filed against us alleging that the our iUni G2 and iDuo G2 partial knee replacement surgical techniques infringe one or more claims of United States Patent No. 6,575,980. We believes that none of our products or services infringes the plaintiff s patent. We intend to deny liability and to defend ourselves vigorously. We presently are unable to predict the outcome of

the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit.

Off-balance sheet arrangements

Through September 30, 2015, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical accounting policies and significant judgments and use of estimates

We have prepared our consolidated financial statements in conformity with accounting principles generally accepted in the United States. Our preparation of these financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting periods. The accounting estimates that require our most significant estimates include revenue recognition, accounts receivable valuation, inventory valuations, intangible valuation, equity instruments, impairment assessments, income tax reserves and related allowances, and the lives of property and equipment. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies are described under the heading Management s Discussion and Analysis of Financial Condition and Results of Operations Critical accounting policies and significant judgments and use of estimates in the Prospectus and Note B to the consolidated financial statements appearing in this Quarterly Report on Form 10-Q.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606) . ASU No. 2014-09 outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new guidance was to be effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2017; early adoption was permitted for annual reporting periods beginning after December 15, 2016, including interim reporting periods within those annual periods. Companies have the option of using either a full retrospective or a modified retrospective approach to adopt the guidance. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of the guidance contained in ASU 2014-09 by one year. Thus, the guidance is effective for the Company commencing in the first quarter of 2019. The Company does not expect that the adoption of ASU 2014-09 will have a material effect on its consolidated financial statements.

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

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In April 2015, the FASB issued ASU No. 2015-05, Intangibles Goodwill and Other Internal-Use Software (Subtopic 350-40): Customer s Accounting for Fees Paid in a Cloud Computing Arrangement (ASU 2015-05), which provides guidance to clarify the customer s accounting for fees paid in a cloud computing arrangement. This guidance is effective for annual periods and interim reporting periods of public entities beginning after December 15, 2015. The Company does not expect that the adoption of ASU 2015- 05 will have a material effect on its consolidated financial statements.

In August 2014, FASB issued ASU No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40) Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern (ASU 2014-15). This newly issued accounting standard provides guidance about management s responsibility to evaluate whether there is a substantial doubt about an entity s ability to continue as a going concern and to provide related footnote disclosures. The defined term substantial doubt requires an evaluation of every reporting period including interim periods, provides principles for considering the mitigating effect of management s plans, requires certain disclosures when substantial doubt is alleviated as a result of consideration of management s plans, requires an express statement and other disclosures when substantial doubt is not alleviated, and requires an assessment for a period of one year after the date that the financial statements are issued or available to be issued. The amendments in ASU 2014-15 are effective for annual periods beginning after December 15, 2016 and interim periods within those reporting periods. Earlier adoption is permitted. The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to various market risks, which may result in potential losses arising from adverse changes in market rates, such as interest rates and foreign exchange rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes and do not believe we are exposed to material market risk with respect to our cash and cash equivalents.

Interest rate risk

We are exposed to interest rate risk in connection with borrowings made under the Revolving Line provided under the 2014 Secured Loan Agreement, which bears interest at a floating rate based on the prime rate. For variable rate debt, interest rate changes generally do not affect the fair value of the debt instrument, but do impact future earnings and cash flows, assuming other factors are held constant. A hypothetical 100 basis point change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Foreign currency exchange risk

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies could adversely affect our financial results. Approximately 22% of our product revenue for the three months ended September 30, 2015 and 27% of our product revenue for the three months ended September 30, 2014 were denominated in foreign currencies. Approximately 26% of our product revenue for the nine months ended September 30, 2015 and 30% of our product revenue for the nine months ended September 30, 2014 were denominated in foreign currencies. We expect that foreign currencies will continue to

represent a similarly significant percentage of our net sales in the future. Costs of revenue related to these sales are primarily denominated in U.S. dollars; however, operating costs, including sales and marketing and general and administrative expense, related to these sales are largely denominated in the same currencies as the sales, thereby partially limiting our transaction risk exposure. Additionally, fluctuations in foreign currency exchange rates may cause us to recognize transaction gains and losses in our statement of operations. To date, foreign currency transaction realized gains and losses have not been material to our consolidated financial statements, and we have not engaged in any foreign currency hedging transactions. As our international operations grow, we will continue to reassess our approach to managing the risks

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relating to fluctuations in currency rates. A 10% increase or decrease in foreign currency exchange rates would not have had a material impact on our consolidated financial statements for the three months ended September 30, 2015 or for the three months ended September 30, 2014. A 10% increase or decrease in foreign currency exchange rates would have resulted in additional income or expense of $0.4 million for the nine months ended September 30, 2015 and $0.4 million for the nine months ended September 30, 2014.

We do not believe that inflation and change in prices had a significant impact on our results of operations for any periods presented in our consolidated financial statements.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2015. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure 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 ensure 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 principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three and nine months ended September 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings.

In the course of our manufacture and sale of joint replacement products, we are subject to routine risk of product liability, patent infringement and other claims in the United States and in other countries where we sell our products.

On September 3, 2015, a class action lawsuit was filed against us and certain of our officers in the United States District Court for the District of Massachusetts, Eastern Division by Henry J. Klein on behalf of stockholders who purchased our common stock in connection with our initial public offering or on the open market between July 1, 2015 and August 28, 2015, which we refer to as the class period. The complaint asserts claims under Sections 11 and 15 of the Securities Act of 1933, as amended, Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, including allegations that our stock was artificially inflated during the class period because we and certain officers allegedly made misrepresentations or did not make proper disclosures regarding our manufacturing process prior to our voluntary recall of specific serial numbers of patient-specific instrumentation for certain of our knee replacement product systems. Specifically, the complaint alleges that statements made during the class period were false and misleading because our manufacturing processes were flawed and, as a result of such flaws, a number of our knee replacement product systems were defective. The complaint seeks, among other relief, class certification of the lawsuit, unspecified compensatory damages, interest, attorneys fees, expert fees and other costs. We believe we have valid defenses to the claims in the lawsuit, will deny liability and intend to defend ourselves vigorously. There can be no assurance, however, that we will be successful. An adverse resolution of the lawsuit could have a material adverse effect on our business, financial condition or results of operations. We are presently unable to predict the outcome of the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit. Additional complaints also may be filed against us and our directors and officers related to our voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems.

On October 21, 2015, a complaint for patent infringement was filed against us in the United States District Court for the District of Delaware by Orthopedic Innovations, Inc., which the complaint states is a subsidiary of Wi-LAN Technologies Inc. The complaint alleges that our iUni G2 and iDuo G2 partial knee replacement surgical techniques infringe one or more claims of United States Patent No. 6,575,980. The plaintiff seeks damages, including for willful infringement, attorney s fees, costs and a permanent injunction. We believe that none of our products or services infringes the plaintiff s patent. We intend to deny liability and to defend ourselves vigorously. There can be no assurance, however, that we will be successful. An adverse resolution of the lawsuit could have a material adverse effect on our business, financial condition or results of operations. We are presently unable to predict the outcome of the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit.

We currently are not a party to any other material legal proceedings.

Item 1A. Risk Factors.

There have been no material changes in the Company s risk factors from those previously disclosed in our final prospectus dated June 30, 2015 for our initial public offering and filed with the Securities and Exchange Commission on July 1, 2015 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, which we refer to as the Prospectus , except for the following risk factors:

We have conducted a voluntary product recall and in the future our products may be subject to additional product recalls either voluntarily or at the direction of the FDA or another governmental authority that could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. On August 31, 2015, we announced a voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems. We have also experienced other limited recalls in the past, related to manufacturing defects, labeling updates and packaging inconsistencies.

We initiated the voluntary recall announced on August 31, 2015 in response to three complaints of excess moisture on patient-specific instrumentation. Based on our investigation into the cause of the excess moisture, we believe that the affected instrumentation underwent the commonly used ethylene oxide sterilization process in the presence of excess water and, as a result, contained small amounts of ethylene glycol residue. Ethylene glycol residue may form when ethylene oxide comes into contact with water. We temporarily suspended our use of the ethylene oxide sterilization process on August 28, 2015. We completed final testing, including an independent test determining that the ethylene glycol residue on the affected instrumentation posed no significant hazard to patients, implemented corrective actions, and resumed normal production in October 2015.

A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. We are also required to follow detailed recordkeeping requirements for all company-initiated medical device corrections and removals and to report such corrective and removal actions to the FDA if they are carried out in response to a risk to health and have not otherwise been reported under the MDR regulations. We may initiate voluntary recalls involving our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall

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announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

In addition, in October 2014, the FDA issued guidance intended to assist the FDA and medical device industry in distinguishing medical device recalls from device enhancements. Per the guidance, if any change or group of changes to a device addresses a violation of the FDCA, that change would generally constitute a medical device recall and not simply a product enhancement and would require submission of a recall report to the FDA.

Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers demands. We may also be subject to liability claims or may be required to bear other costs or to take other actions that may have a negative impact on our future sales and our ability to generate profits.

In particular, our voluntary recall announced on August 31, 2015 has adversely affected our business and may continue to adversely affect our business in a number of ways, including through the financial impact from lost sales of the recalled products, reduction of our production capacity over the period of our investigation and resolution of the root cause of the recall, commercial disruption, damage to our reputation with consumers, healthcare providers, distributors and other business partners, and the filing of a putative class action complaint against us and certain of our officers alleging violations of securities laws.

We may encounter problems or delays in the manufacturing of our products or fail to meet certain regulatory requirements that could result in a material adverse effect on our business and financial results.

We historically manufactured a portion of our products at our facilities in Burlington, Bedford and Wilmington, Massachusetts. We transitioned our manufacturing operations at our Burlington facility to our Wilmington facility in July 2015; we vacated our Burlington facility in August 2015. We are continuing the build out of our manufacturing capabilities at our Wilmington facility. Manufacturing processes in our Bedford and Wilmington facilities require manufacturing validation and are subject to FDA inspections, as well as inspections by international regulatory agencies, including Notified Bodies for the European Union. We have completed the validation of our manufacturing processes for implant components and instrumentation manufactured at our new Wilmington facility. Delays in validation or FDA registration of new manufacturing processes could impact our ability to grow our business in the future.

On August 31, 2015, we announced a voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems. The recalled patient-specific instruments were manufactured and distributed from our new Wilmington manufacturing facility between July 18, 2015 and August 28, 2015. While we have since completed final testing, implemented corrective actions, and resumed normal production in October 2015, this recall and the resulting temporary reduction in capacity has adversely affected our business and may continue to adversely affect our business.

Our current and planned future products are complex and require the integration of a number of separate components and processes. To become profitable, we must manufacture our products in increased quantities in compliance with regulatory requirements and at an acceptable cost. Increasing our capacity to manufacture our products on this scale will require us to introduce new manufacturing processes, including direct

metal laser sintering, or DMLS, 3D printing of metal implant components and vertical integration of the manufacturing process by performing machining, polishing and other finishing services in-house, and to improve internal efficiencies. To date, we have not used 3D printing technology to manufacture commercially the metal implants that are used in our joint replacement systems. In addition, we have limited commercial manufacturing experience with respect to our iTotal PS knee and no commercial manufacturing experience yet with respect to our iTotal Hip replacement products.

If we are unable to satisfy commercial demand for our products due to our inability to manufacture them in compliance with applicable laws and regulations, or due to temporary or permanent reduced manufacturing capabilities, our business and financial results, including our ability to generate revenue, would be impaired, market acceptance of our products could be diminished and customers may instead purchase our competitors products.

We may encounter other difficulties in increasing and expanding our manufacturing capacity, including difficulties:

- acquiring raw materials for 3D printing;
- deploying new manufacturing processes, including DMLS 3D printing;
- acquiring 3D printers, especially DMLS 3D printers;
- managing production yields;

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- maintaining quality control and assurance;
- maintaining component availability;
- maintaining adequate control policies and procedures;
- hiring and retaining qualified personnel; and
- complying with state, federal and foreign regulations.

Moreover, any significant disruption of our manufacturing operations or damage to our facilities or stores of raw materials for any reason, such as fire or other events beyond our control, including as a result of natural disasters or terrorist attacks, could adversely affect our sales and customer relationships and therefore adversely affect our business.

The medical device industry is characterized by frequent patent litigation, and we could become subject to litigation that could be costly, result in the diversion of management s time and efforts, require us to pay damages or prevent us from marketing our existing or future products.

Our commercial success depends in part on not infringing the patents or violating the other proprietary rights of others and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or products, including interference or derivation proceedings before the U.S. Patent and Trademark Office. Significant litigation regarding patent rights occurs in our industry. 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 may prevent, limit or otherwise interfere with our ability to make, use and sell our products. Our ability to defend ourselves or our third-party suppliers may be limited by our financial and human resources, the availability of reasonable defenses, and the ultimate acceptance of our defenses by the courts or juries. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, so there may be applications of others now pending of which we are unaware that may later result in issued patents that may prevent, limit or otherwise interfere with our ability to make, use or sell our products. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved and the uncertainty of litigation increase the risk of business assets and management s attention being diverted to patent litigation.

We have received in the past, and may receive in the future, particularly as a public company, communications from various industry participants and patent holders alleging our infringement of their patents, trade secrets or other intellectual property rights or offering licenses to such intellectual property. We are aware of non-practicing entities that are seeking to exploit patents in the orthopedic area. In particular, in October 2015 we were sued for patent infringement by one such non-practicing entity, Orthopedics Innovations, Inc., alleging that our iUni G2 and iDuo G2 partial knee replacement surgical techniques infringe an existing patent. Among other relief, the plaintiff seeks damages for willful

infringement, attorney s fees, costs and a permanent injunction. This lawsuit is described in more detail in Part II, Item 1, *Legal Proceedings*, of this Quarterly Report on Form 10-Q. While we believe we have meritorious defenses, we cannot predict the outcome of this lawsuit.

Lawsuits resulting from allegations of infringement could, if successful, subject us to significant liability for damages and invalidate our proprietary rights. We have in the past settled allegations of infringement by entering into a settlement and license agreement and may need to do so again in the future. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;

- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;

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- incur significant legal expenses;

- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;

- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;

- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive or infeasible; or

- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

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 joint replacement industry grows, the possibility of intellectual property infringement claims against us increases. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages, which may be increased up to three times of awarded damages, or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition.

In addition, any claims that we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. As part of our intellectual property strategy, we plan to continue pursuing opportunities to assert our patents and intellectual property portfolio to secure agreements from other companies to pay royalties or make other payments to us with respect to their products that incorporate our technology. This activity could potentially bring unwanted attention to or scrutiny of our patent and intellectual property portfolio.

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We also have identified the following risk factor in addition to the risks factors previously disclosed in our Prospectus:

We are currently subject to securities class action litigation and may be subject to similar or other litigation in the future, which may divert management s attention and have a material adverse effect on our business, financial condition and results of operations.

On September 3, 2015, a class action lawsuit was filed against us and certain of our officers in the United States District Court for the District of Massachusetts, Eastern Division, alleging, among other things, that we and certain of our officers violated federal securities laws because we and certain of our officers allegedly made misrepresentations or did not make proper disclosures regarding our manufacturing process prior to our voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems. Among other relief, the plaintiff seeks class certification of the lawsuit, unspecified compensatory damages, interest, attorneys fees, expert fees and other costs. The class action lawsuit is described in more detail in Part II, Item 1, *Legal Proceedings*, of this Quarterly Report on Form 10-Q.

While we believe we have meritorious defenses, we cannot predict the outcome of this lawsuit. There may be additional suits or proceedings brought in the future related to our voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems. Monitoring and defending against legal actions, whether or not meritorious, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities, and we cannot predict how long it may take to resolve such matters. In addition, we may incur substantial legal fees and costs in connection with litigation. Although we have insurance, coverage could be denied or prove to be insufficient. We are not currently able to estimate the possible cost to us from this lawsuit, as the complaint has only recently been filed, and we cannot be certain how long it may take to resolve or the possible amount of any damages, if any, that we may be required to pay. We have not established any reserves for any potential liability relating to this lawsuit. It is possible that we could, in the future, incur judgment or enter into settlement of claims for monetary damages. A decision adverse to our interests on this lawsuit could result in the payment of substantial damages and could have a material adverse effect on our business, results of operations and financial condition. In addition, the uncertainty of the currently pending lawsuit could lead to more volatility in our stock price.

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

Use of proceeds from registered securities

On July 7, 2015, we closed our initial public offering, or IPO, of our common stock and issued and sold 10,350,000 shares of our common stock, including 1,350,000 shares of common stock issued upon the exercise in full by the underwriters of their over-allotment option, at a public offering price of $15.00 per share, for aggregate offering proceeds of approximately $155 million.

The offer and sale of all of the shares in the offering was registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-204384), which was declared effective by the SEC on June 30, 2015.

We received aggregate net proceeds from the offering of approximately $140 million after deducting underwriting discounts and commissions and offering expenses payable by us. None of the underwriting discounts and commissions or offering expenses were incurred or paid to any director or officer of ours, to any of their associates, to persons owning 10% or more of our common stock or to any affiliates of ours.

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As of September 30, 2015, we have used approximately $20.5 million of the net proceeds from the offering as follows: $0.9 million to purchase and install capital equipment to expand our manufacturing capacity, approximately $10.0 million to expand and support our sales and marketing efforts, and approximately $3.9 million to fund research, development and clinical activities and approximately $5.7 million for other general corporate purposes. We have not used any of the net proceeds from our IPO to make payments, directly or indirectly, to any director or officer of ours, to any of their associates, to persons owning 10% or more of our common stock or to any affiliates of ours. We have invested the remaining net proceeds from the offering in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities. There has been no material change in our planned use of the net proceeds from the initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on July 1, 2015.

Issuance of stock upon the exercise of warrants and conversion of warrants to purchase preferred stock

On July 7, 2015, we issued 380,902 shares of our common stock upon the cash exercise or exchange of warrants to purchase our capital stock, which consisted of warrants to purchase:

- 4,166 shares of our common stock at an exercise price of $4.32 per share;
- 5,555 shares of our Series D preferred stock at an exercise price of $6.00 per share;
- 246,874 shares of our Series D preferred stock in exchange for the surrender of warrants to purchase 246,874 shares of our Series D preferred stock;
- 300,059 shares of our Series E-1 preferred stock at an exercise price of $8.00 per share; and
- 200,996 shares of our Series E-2 preferred stock at an exercise price of $8.00 per share.

In addition, each of the following occurred on July 7, 2015:

- a warrant to purchase 285,714 shares of our Series C preferred stock at an exercise price of $3.50 per share converted into a warrant to purchase 142,857 shares of our common stock at an exercise price of $7.00 per share; and

- a warrant to purchase 160,000 shares of our Series D preferred stock at an exercise price of $6.00 per share converted into a warrant to purchase 80,000 shares of our common stock at an exercise price of $12.00 per share.

The shares of common stock issued pursuant to the warrant exercises and warrant exchange, and the converted warrants to purchase common stock, were issued to accredited investors in reliance upon the exemption provided by Section 4(a)(2) of the Securities Act of 1933 relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. The recipients of securities in these issuances represented that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time and appropriate legends were affixed to the instruments representing such securities issued in such transactions. No underwriters were involved in these issuances of securities.

Item 6. **Exhibits.**

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

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SIGNATURES

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

CONFORMIS, INC.

Date: November 9, 2015

By: /s/ Paul Weiner
Paul Weiner

Chief Financial Officer

(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Description of Exhibit
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Database
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

* This certification will not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.