ConforMIS Inc
Form 10-Q
August 11, 2016

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

OR

¨ 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 ¨

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 ¨

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 ¨ No x

As of July 31, 2016, there were 42,127,152 shares of Common Stock, $0.00001 par value per share, outstanding.

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)

	June 30, 2016 (unaudited)	December 31, 2015
Assets		
Current Assets		
Cash and cash equivalents	$ 37,813	$ 117,185
Investments	44,749	—
Accounts receivable, net	13,078	14,867
Inventories	11,977	11,520
Prepaid expenses and other current assets	1,825	2,451
Total current assets	109,442	146,023
Property and equipment, net	13,736	10,966
Other Assets		
Restricted cash	300	600
Investments	5,003	—
Intangible assets, net	870	995
Goodwill	753	753
Other long-term assets	29	32
Total assets	$ 130,133	$ 159,369
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,222	$ 4,718
Accrued expenses	6,838	7,811
Deferred revenue	305	305
Current portion of long-term debt	307	295
Total current liabilities	9,672	13,129
Other long-term liabilities	167	220
Deferred revenue	4,472	4,625
Long-term debt	27	183
Total liabilities	14,338	18,157
Commitments and contingencies	—	—
Stockholders’ equity		
Preferred stock, $0.00001 par value: Authorized: 5,000,000 shares authorized as of June 30, 2016 and December 31, 2015; no shares issued and outstanding as of June 30, 2016 and December 31, 2015	—	—
Common stock, $0.00001 par value: Authorized: 200,000,000 shares authorized as of June 30, 2016 and December 31, 2015; 42,122,052 and 41,110,127 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	—	—
Additional paid-in capital	470,867	467,075
Accumulated deficit	(354,428)	(325,342)
Accumulated other comprehensive loss	(644)	(521)

Total stockholders' equity	115,795	141,212
Total liabilities and stockholders' equity	$ 130,133	$ 159,369

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

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue				
Product	$19,104	$15,763	$39,086	$30,463
Royalty	229	3,459	497	3,459
Total revenue	19,333	19,222	39,583	33,922
Cost of revenue	13,332	11,395	26,919	21,239
Gross profit	6,001	7,827	12,664	12,683
Operating expenses				
Sales and marketing	10,648	9,027	21,762	18,151
Research and development	3,977	4,317	8,375	8,333
General and administrative	5,487	5,355	11,782	11,134
Total operating expenses	20,112	18,699	41,919	37,618
Loss from operations	(14,111)	(10,872)	(29,255)	(24,935)
Other income and expenses				
Interest income	143	28	282	68
Interest expense	(75)	(245)	(100)	(469)
Other income (expense)	—	208	—	208
Total other income/(expenses), net	68	(9)	182	(193)
Loss before income taxes	(14,043)	(10,881)	(29,073)	(25,128)
Income tax provision	9	11	13	21
Net loss	$(14,052)	$(10,892)	$(29,086)	$(25,149)
Net loss per share - basic and diluted	$(0.34)	$(2.51)	$(0.71)	$(5.82)
Weighted average common shares outstanding - basic and diluted	41,314,942	4,341,784	41,155,421	4,319,334

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

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss
(unaudited)
(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss	$(14,052)	$(10,892)	$(29,086)	$(25,149)
Other comprehensive income (loss)				
Foreign currency translation adjustments	(276)	218	(134)	214
Change in unrealized gain (loss) on available-for-sale securities, net of tax	2	—	11	—
Comprehensive loss	$(14,326)	$(10,674)	$(29,209)	$(24,935)

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

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Six Months Ended June 30,	
	2016	2015
Cash flows from operating activities		
Net loss	$(29,086)	$(25,149)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization expense	1,543	1,199
Amortization of debt discount	3	21
Stock-based compensation expense	2,131	1,846
Provision for bad debts on trade receivables	190	164
Amortization/accretion on investments	128	—
Tax effect, unrealized gain/loss on investments	(6)	—
Changes in operating assets and liabilities:		
Accounts receivable	1,599	(2,075)
Inventories	(457)	(1,688)
Prepaid expenses and other assets	629	(248)
Deferred initial public offering costs	—	(4,489)
Accounts payable and accrued liabilities	(3,469)	3,942
Deferred royalty revenue	(153)	5,084
Other long-term liabilities	(53)	(25)
Net cash used in operating activities	(27,001)	(21,418)
Cash flows from investing activities:		
Acquisition of property and equipment	(4,188)	(2,977)
Decrease (increase) in restricted cash	300	109
Purchase of investments	(55,363)	—
Maturity of investments	5,500	—
Net cash used in investing activities	(53,751)	(2,868)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	1,661	389
Proceeds from exercise of preferred stock warrant	—	416
Payments on long-term debt	(147)	(137)
Net cash provided by financing activities	1,514	668
Foreign exchange effect on cash and cash equivalents	(134)	214
(Decrease) increase in cash and cash equivalents	(79,372)	(23,404)
Cash and cash equivalents, beginning of period	117,185	37,900
Cash and cash equivalents, end of period	$37,813	$14,496

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

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 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 (the "IPO") 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 June 30, 2016, the Company had an accumulated deficit of $354.4 million.

The Company’s principal sources of funds are revenue generated from the sale of its products and the net proceeds from the IPO.

As of June 30, 2016, the Company had cash and cash equivalents, and short-term and long-term investments of $87.6 million and $0.3 million in restricted cash allocated to lease deposits. As of December 31, 2015, the Company had cash and cash equivalents of $117.2 million and $0.6 million in restricted cash allocated to lease deposits.

As of June 30, 2016, based on its current operating plan, the Company expects that its existing cash and cash equivalents as of June 30, 2016 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.

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

Unaudited Interim Financial Information

The accompanying Interim Consolidated Financial Statements as of June 30, 2016 and for the three and six months ended June 30, 2016 and 2015, 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 generally accepted accounting principles in the United States, or 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 June 30, 2016, results of operations for the three and six months ended June 30, 2016 and 2015, and cash flows for the six months ended June 30, 2016 and 2015. The results for the three and six months ended June 30, 2016 are not necessarily indicative of the results expected for the full year or any interim period.

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 consist of cash, cash equivalents, investments, and accounts receivable. The Company maintains the majority of its cash and investments 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 six months ended June 30, 2016 and 2015, no customer represented greater than 10% of revenue. There were no customers that represented greater than 10% of total gross receivable balance as of June 30, 2016 or December 31, 2015.

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 consist 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. The associated risk of concentration is mitigated by banking with credit worthy financial institutions.

The Company had $9.1 million as of June 30, 2016 and $2.1 million as of December 31, 2015 held in foreign bank accounts. In addition, the Company has recorded restricted cash of $0.3 million as of June 30, 2016 and $0.6 million as of December 31, 2015. Restricted cash consisted of security provided for lease obligations.

Investment securities

The Company classifies its investment securities as available-for-sale. Those investments with maturities less than 12 months at the date of purchase are considered short-term investments. Those investments with maturities greater than 12 months at the date of purchase are considered long-term investments. The Company's investment securities classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses, deemed temporary in nature, are reported as a separate component of accumulated other comprehensive income (loss).

A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Premiums (discounts) are amortized (accreted) over the life of the related security the constant yield method. Dividend and interest income are recognized when earned and reported in other income. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of securities sold.

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. Financial instruments including money market funds and investments are carried at fair value.

Accounts receivable and allowance for doubtful accounts

Accounts receivable consist 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 consist 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.

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 consist 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 six months ended June 30, 2016 and 2015, 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. During the six months ended June 30, 2016, and 2015, there were no triggering events which would require an interim goodwill impairment assessment.

Revenue recognition

Product

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, Germany, the United Kingdom, Ireland, Austria, Switzerland, Singapore and Hong Kong.

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.

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.

Royalty

The Company has accounted for royalty agreements with Wright Medical Group, Inc. and MicroPort Orthopedics, Inc. 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. 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.

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 consist of engineering, product development, quality assurance, clinical and regulatory expense. These costs primarily relate 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, which are included in sales and marketing, are expensed as incurred. Advertising expense was $73,000 and $35,000 for the three months ended June 30, 2016 and 2015, respectively, and was $183,000 and $151,000 for the six months ended June 30, 2016 and 2015, respectively.

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 J—Segment and Geographic Data".

Comprehensive loss

As of June 30, 2016 and 2015, accumulated other comprehensive loss consists of foreign currency translation adjustments and changes in unrealized gain and loss of available-for-sale securities, net of tax.

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 as of the balance sheet date, and income and expense items are translated at average rates of exchange prevailing during the period. 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. Valuation allowance is maintained to reduce deferred tax assets to the amount expected to be realized.

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.

The Company is subject to U.S. federal, state, and foreign income taxes. The Company recorded a provision for income taxes of approximately $9,000 and $11,000 for the three months ended June 30, 2016 and 2015, respectively, and $13,000 and $21,000 for the six months ended June 30, 2016 and 2015, respectively.

The Company recognizes interest and penalties related to income taxes as a component of income tax expense. As of June 30, 2016 and December 31, 2015, $9,000 and $6,000 of interest and penalties have been accrued, respectively.

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 Consolidated Appropriations Act of 2016 includes a two-year moratorium on the medical device excise tax, which moratorium suspended taxes on the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016 and ending on December 31, 2017. The Company incurred medical device excise tax expense of $0 million and $0.2 million for the three months ended June 30, 2016 and 2015, respectively, and $0 million and $0.4 million for the six months ended June 30, 2016 and 2015, 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 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 I—Stockholders’ Equity” for a summary of the stock option activity under the Company’s stock-based compensation plan.

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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):

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands, except share and per share data)	2016	2015	2016	2015
Numerator:				
Numerator for basic and diluted loss per share:				
Net loss	$(14,052)	$(10,892)	$(29,086)	$(25,149)
Denominator:				
Denominator for basic loss per share:				
Weighted average shares	41,314,942	4,341,784	41,155,421	4,319,334
Basic loss per share attributable to ConforMIS, Inc. stockholders	$(0.34)	$(2.51)	$(0.71)	$(5.82)
Diluted loss per share attributable to ConforMIS, Inc. stockholders	$(0.34)	$(2.51)	$(0.71)	$(5.82)

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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Series A Preferred	—	1,705,138	—	1,705,138
Series B Preferred	—	2,234,668	—	2,234,668
Series C Preferred	—	2,453,018	—	2,453,018
Series D Preferred	—	6,657,880	—	6,655,764
Series E-1 Preferred	—	7,316,743	—	7,316,743
Series E-2 Preferred	—	5,129,590	—	5,129,590
Series C Preferred Warrants	—	76,191	—	76,191
Series D Preferred Warrants	—	109,926	—	109,926
Common stock warrants	44,659	83,119	61,169	83,119
Stock options and restricted stock awards	2,120,712	3,600,092	2,286,613	3,593,586
Total	2,165,371	29,366,365	2,347,782	29,357,743

Recent accounting pronouncements

In June 2016, the FASB issued ASU No. 2016-12, "Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients" ("ASU 2016-12") which provides guidance for accounting of credit losses affecting the impairment model for most financial assets and certain other instruments. Entities will be required to use a new forward-looking current expected credit loss model for trade and other receivables, held-to-maturity debt securities, loans and other instruments, which will generally lead to an earlier recognition of loss allowances. Entities will recognize losses on available-for-sale debt securities as allowances rather than a reduction in amortized cost of the security while the measurement process of this loss does not change. Disclosure requirements

are expanded regarding an entity's assumptions, models and methods of estimations of the allowance. The guidance will be effective in the first quarter of 2020, with the option for early adoption. The

Company is currently evaluating the impact of this pronouncement on its consolidated financial statements and expects to adopt this pronouncement commencing in the first quarter of 2020.

In April 2016, the FASB issued ASU 2016-10, "Identifying Performance Obligations and Licensing" ("ASU 2016-10"). This ASU clarifies two aspects of ASU 2014-09, "Revenue from Contracts with Customers (Topic 606): identifying performance obligations and the licensing implementation guidance". ASU 2016-10 will become effective for the first quarter of 2018. The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements and expects to adopt this pronouncement commencing in the first quarter of 2018.

In March 2016, the FASB issued ASU No. 2016-08, "Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)" ("ASU 2016-08") which clarifies the implementation guidance on principal versus agent considerations. The guidance includes indicators to assist an entity in determining whether it controls a specified good or service before it is transferred to the customers. This guidance will be effective in the first quarter of 2018, with the option to adopt it in the first quarter of 2017. The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements and expects to adopt this pronouncement commencing in the first quarter of 2018.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation—Stock Compensation (Topic 718)" ("ASU 2016-09"). This standard makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation and the financial statement presentation of excess tax benefits or deficiencies. ASU 2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, although early adoption is permitted. The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements and expects to adopt this pronouncement commencing in the first quarter of 2017.

Reclassification

During the quarter ended June 30, 2016, the Company identified that certain costs of revenue had been improperly classified as sales and marketing expense in the Consolidated Statements of Operations. The Company has concluded that the prior classification was an error and that it is immaterial to all annual and quarterly periods previously presented. However, to facilitate period-over-period comparisons, the Company has revised its prior period financial statements to reflect the corrections in the period in which the expenses were incurred. As a result, the Company reclassified $0.7 million and $1.2 million from sales and marketing to cost of revenue for the three and six months ended June 30, 2015, respectively. In addition, the Company reclassified $0.4 million for the three months ended March 31, 2016 from sales and marketing to cost of revenue. These reclassifications did not have any impact on loss from operations, net loss per share - basic and diluted or accumulated deficit. For year-over-year comparison, the Company incurred related expense, included in cost of revenue, of $1.2 million and $1.6 million for the three and six months ended June 30, 2016, respectively.

Note C—Fair Value Measurements

The Fair Value Measurements topic of the FASB Codification establishes a framework for measuring fair value in accordance with U.S. 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.
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 Company's investment policy is consistent with the definition of available-for-sale securities. All investments have been classified within Level 1 or Level 2 of the fair value hierarchy because of the sufficient observable inputs for revaluation. The Company's Level 1 cash equivalents and investments are valued using quoted prices that are readily and regularly available in an active market. The Company's Level 2 investments are valued using third-party pricing sources based on observable inputs, such as quoted prices for similar assets at the measurement date; quoted prices in markets that are not active; or other inputs that are observable, either directly or indirectly.

The following table summarizes, by major security type, the Company's assets that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy and where they are classified on the Consolidated Balance Sheets (in thousands):

	June 30, 2016						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and cash equivalents	Short-term (1) investments	Long-term (2) investments
Cash	$16,378	$ —	$ —	$16,378	$ 16,378	$ —	$ —
Level 1 securities:							
Money market funds	21,435	—	—	21,435	21,435	—	—
U.S. treasury bonds	5,010	2	—	5,012	—	5,012	—
Level 2 securities:							
Corporate bonds	14,085	6	(3)	14,088	—	14,088	—
Commercial paper	7,488	—	—	7,488	—	7,488	—
Agency bond	23,151	13	—	23,164	—	18,161	5,003
Total	$87,547	$ 21	$ (3)	$87,565	$ 37,813	$ 44,749	$ 5,003

(1) Contractual maturity due within one year.
(2) Contractual maturity greater than one year.

	December 31, 2015						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and cash equivalents	Short-term investments	Long-term investments
Cash	$10,302	$ —	$ —	$10,302	$ 10,302	$ —	$ —
Level 1 securities:							
Money market funds	106,883	—	—	106,883	106,883	—	—
Total	$117,185	$ —	$ —	$117,185	$ 117,185	$ —	$ —

Realized gains or losses and other-than-temporary impairments, if any, on available-for-sale securities are reported in other income (expense), net as incurred. The Company did not have material unrealized losses at June 30, 2016. There were no material gross realized gains or losses in the three and six months ended June 30, 2016.

Note D—Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	June 30, 2016	December 31, 2015
Total receivables	$13,839	$ 15,421
Allowance for doubtful accounts and returns	(761)	(554)
Accounts receivable, net	$13,078	$ 14,867

There were $0 and $64,000 write-offs related to accounts receivable for the three months ended June 30, 2016 and 2015, respectively, and $0 and $64,000 for the six months ended June 30, 2016 and 2015, respectively.

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Summary of allowance for doubtful accounts and returns activity was as follows (in thousands):

	June 30, 2016	December 31, 2015
Beginning balance	(554)	(162)
Provision for bad debts on trade receivables	(190)	(359)
Other allowances	(17)	(121)
Accounts receivable write offs	—	88
Ending balance	$(761)	$ (554)

Note E—Inventories

Inventories consisted of the following (in thousands):

	June 30, 2016	December 31, 2015
Raw Material	$4,135	$ 4,175
Work in process	2,010	2,683
Finished goods	5,832	4,662
Total Inventories	$11,977	$ 11,520

As of June 30, 2016 and December 31, 2015, inventories included write-downs of $0.3 million and $0.3 million and reserves of $0 and $37,000, respectively, for estimated surgery cancellations related to units affected by the voluntary recall of specific serial numbers of patient-specific instrumentation for the Company's iUni, iDuo, iTotal CR, and iTotal PS knee replacement product systems in August 2015 and sterilization capacity limitation.

Note F—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2016	December 31, 2015
Accrued employee compensation	$ 3,072	$ 3,585
Deferred rent	199	213
Accrued legal expense	1,040	334
Accrued consulting expense	18	134
Accrued vendor charges	365	692
Accrued revenue share expense	868	932
Accrued patent settlement and license costs	—	500
Accrued clinical trial expense	146	302
Accrued other	1,130	1,119
	$ 6,838	$ 7,811

Note G—Commitments and Contingencies

Operating Leases - Real Estate

The Company maintains its corporate headquarters in a leased building located in Bedford, Massachusetts, and its manufacturing 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 Company leases the Wilmington facility under a long-term, non-cancellable lease that commenced in

April 2015 and will expire in July 2022.

Rent expense of $0.4 million and $0.5 million for the three months ended June 30, 2016 and 2015, respectively, and $0.7 million and $0.8 million for the six months ended June 30, 2016 and 2015, respectively, was charged to operations. 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.

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 0.1% 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 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 revenue share expense paid to Dr. Lang of $238,000 and $195,000 for the three months ended June 30, 2016, and 2015, respectively, and $487,000 and $376,000 for the six months ended June 30, 2016, and 2015, respectively.

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 $0.9 million during the three months ended June 30, 2016, representing 4.7% of product revenue, $1.7 million during the six months ended June 30, 2016, representing 4.3% of product revenue, $0.8 million during the three months ended June 30, 2015, representing 5.1% of product revenue, and $1.6 million during the six months ended June 30, 2015, representing 5.2% of product revenue. Revenue share expense is included in research and development. See "Note H—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.

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 H—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. 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 the Company 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 June 30, 2016 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.

Revenue share agreement

As described in "Note G—Commitments and Contingencies", 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 its net revenues, ranging from 0.875% to 1.33%, with respect to all of its 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 $238,000 and $195,000 and for the three months ended June 30, 2016 and 2015, respectively, and $487,000 and $376,000 for the six months ended June 30, 2016 and 2015, respectively.

Note I—Stockholders' Equity

Common stock

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 is entitled to one vote.

Summary of common stock activity was as follows:

	Shares
Outstanding December 31, 2015	41,110,127
Issuance of common stock - option exercises	539,012
Issuance of restricted common stock	472,913
Outstanding June 30, 2016	42,122,052

Common stock warrants

The Company 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 upon the closing of the Company's IPO to warrants to purchase 564,188 shares of common stock. Warrants to purchase 751,779 shares of common stock were outstanding as of June 30, 2016 and December 31, 2015.

As of June 30, 2016 and December 31, 2015, the weighted average warrant exercise prices per share for common stock underlying warrants and the weighted average contractual life was as follows:

June 30, 2016	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	751,779	$ 10.30	0.83	751,779	$ 10.30

December 31, 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	751,779	$ 10.30	1.33	751,779	$ 10.30

Stock option plans

As of June 30, 2016, 1,738,878 shares of common stock were available for future issuance under the 2015 Stock Incentive Plan ("2015 Plan").

Stock option activity under all stock option plans was as follows:

	Number of Options	Weighted Average Exercise Price per Share
Outstanding December 31, 2015	5,248,329	$ 5.56
Granted	—	—
Exercised	(539,012)	3.08
Expired	(39,164)	10.09
Cancelled/Forfeited	(40,835)	10.17
Outstanding June 30, 2016	4,629,318	$ 5.77
Total vested and exercisable	4,013,969	$ 5.10

The total intrinsic value of awards exercised during the three and six months ended June 30, 2016 was $1.4 million and $2.8 million, respectively. The total fair value of awards that vested during the three and six months ended June 30, 2016 was $0.5 million and $1.1 million, respectively. The weighted average remaining contractual term for the total stock options outstanding was 5.28 years as of June 30, 2016. The weighted average remaining contractual term for the total stock options vested and exercisable was 4.84 years as of June 30, 2016.

Restricted common stock award activity under the plan was as follows:

	Number of Shares	Weighted Average Fair Value
Unvested December 31, 2015	174,530	$ 22.31
Granted	486,297	8.23
Vested	(30,750)	12.86
Forfeited	(13,384)	16.72
Unvested June 30, 2016	616,693	$ 11.80

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.

There were no options granted for the six months ended June 30, 2016.

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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Risk-free interest rate	N/A	1.75%	N/A	1.37% - 1.75%
Expected term (in years)	N/A	6.02 - 6.25	N/A	5.47 - 6.45
Dividend yield	N/A	—%	N/A	—%
Expected volatility	N/A	50.00%	N/A	50.00%

Employee stock-based compensation expense recognized was $1.2 million and $0.8 million for the three months ended June 30, 2016 and 2015, and $2.1 million and $1.8 million for the six months ended June 30, 2016 and 2015. 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.

As of June 30, 2016, the Company had $2.6 million of total unrecognized compensation expense for options that will be recognized over a weighted average period of 1.84 years. As of June 30, 2016, the Company had $6.4 million of total unrecognized compensation expense for restricted awards that will be recognized over a weighted average period of 3.28 years.

Note J—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), Germany and the Rest of World, which consists

predominately of Europe (including the United Kingdom). In general, sales are attributable to a geographic area based upon the customer’s country of domicile. Certain customers in Europe that are located outside of Germany are serviced by the Company's German subsidiary and revenues from those customers are attributable to Germany. Net property, plant and equipment are based upon physical location of the assets.

Geographic information consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Product Revenue				
United States	$15,002	$11,833	29,709	22,130
Germany	3,650	3,492	8,372	7,513
Rest of World	452	438	1,005	820
	$19,104	$15,763	39,086	30,463

	June 30, 2016	December 31, 2015
Property and equipment, net		
United States	$13,613	$ 10,836
Germany	123	130
Rest of World	—	—
	$13,736	$ 10,966

Note K—Subsequent Events

On July 25, 2016, the Company entered into an amendment to the lease for its manufacturing facility located in Wilmington, Massachusetts. Pursuant to the amendment, the Company exercised an option in its current lease to rent an additional 18,223 square feet of space adjacent to the Company's existing premises. The Company is scheduled to take possession of the additional space in March 2017. The initial term of the lease for the existing premises and the additional space expires on July 31, 2022, and the Company has a right to extend the term for one additional five-year term. The initial base rental rate for the additional space is $191,342 annually, subject to 2% annual increases until the expiration of the initial term.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2015. 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’’ section of this Quarterly Report on Form 10-Q, 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,” “p
“should,” “target,” “will,” or “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 submit a new application for 510(k)clearance and 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;
- patent infringement claims;
- the impact of our voluntary recall initiated in August 2015 on our business operations, financial results and customer relations;
- 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 reimposition of the 2.3 percent medical device excise tax if and when the current moratorium is lifted;
- 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, particularly in the "Risk Factors" section, 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 40,000 knee implants in the United States and Europe. In 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. In February 2015, we initiated the limited launch of iTotal PS, our posterior-stabilized total knee replacement implant which addresses the largest segment of the knee replacement market and we initiated the broad commercial launch of the iTotal PS in March 2016.

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 that we may extend to the manufacture of 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 use direct sales representatives, independent sales representatives and distributors to market and sell our products in the

United States, Germany, the United Kingdom 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 in 2015. We initiated the broad commercial launch of our iTotal PS in March 2016.

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, Germany, the United Kingdom, Austria, Ireland, Switzerland, Singapore, and Hong Kong. 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 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.

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.

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. 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. The recalled products were manufactured and distributed from our Wilmington manufacturing facility between July 18, 2015 and

August 28, 2015. We isolated the root cause to a step in our ethylene oxide sterilization process conducted by a vendor. We have since completed final testing and implemented corrective actions, and we resumed normal production in October 2015. 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, slower than expected ramp in new orders and damage to our reputation with orthopedic surgeons, consumers, healthcare providers, distributors and other business partners.

Cost of revenue

We produce all of our computer aided designs, or 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. Since August 2015, we have manufactured 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 the remainder of our customized implant components using the CAD designs we supply. Cost of revenue consists primarily of cost 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, product sales mix, the number of cancelled sales orders and royalty revenue.

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;
- 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 continue to explore the application of our 3D printing technology to select metal components of our products, which we believe may be a future opportunity for reducing our manufacturing costs. 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.

Operating expenses

Our operating expenses consist of sales and marketing, research and development and general and administrative expenses. Personnel costs are the most significant component of operating expenses and consist 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.

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. 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.

Consolidated results of operations

Comparison of the three months ended June 30, 2016 and 2015

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

Three Months Ended June 30,	2016 Amount	2016 As a% of Total Revenue	2015 Amount	2015 As a% of Total Revenue	2016 vs 2015 $ Change	2016 vs 2015 % Change
Revenue						
Product revenue	$19,104	99 %	$15,763	82 %	$3,341	21 %
Royalty	229	1	3,459	18	(3,230)	(93)
Total revenue	19,333	100	19,222	100	111	1
Cost of revenue	13,332	69	11,395	59	1,937	17
Gross profit	6,001	31	7,827	41	(1,826)	(23)
Operating expenses:						
Sales and marketing	10,648	55	9,027	47	1,621	18
Research and development	3,977	21	4,317	22	(340)	(8)
General and administrative	5,487	28	5,355	28	132	2
Total operating expenses	20,112	104	18,699	97	1,413	8
Loss from operations	(14,111)	(73)	(10,872)	(57)	(3,239)	(30)
Total other income/(expenses), net	68	—	(9)	—	77	856
Loss before income taxes	(14,043)	(73)	(10,881)	(57)	(3,162)	(29)
Income tax provision	9	—	11	—	(2)	(18)
Net loss	$(14,052)	(73)%	$(10,892)	(57)%	$(3,160)	(29)%

Product revenue. Product revenue was $19.1 million for the three months ended June 30, 2016 compared to $15.8 million for the three months ended June 30, 2015, an increase of $3.3 million or 21%, due principally to increased sales of our primary total knee products, iTotal CR and iTotal PS.

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):

Three Months Ended June 30,	2016 Amount	2016 As a % of Product Revenue	2015 Amount	2015 As a % of Product Revenue	2016 vs 2015 $ Change	2016 vs 2015 % Change
United States	$15,002	79 %	$11,833	75 %	$3,169	27 %
Germany	3,650	19	3,492	22	$158	5
Rest of world	452	2	438	3	14	3
Product revenue	$19,104	100 %	$15,763	100 %	$3,341	21 %

Product revenue in the United States was generated through our direct sales force and independent sales representatives. Product revenue outside the United States was generated through our direct sales force and distributors. The percentage of product revenue generated in the United States was 79% for the three months ended June 30, 2016 compared to 75% for the three months ended June 30, 2015.

Royalty revenue. 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 the same time we also entered into a worldwide license agreement with MicroPort for a lump-sum payment by MicroPort to us upon entering into the license agreement. Royalty revenue related to these agreements was $0.2 million for the three months ended June 30, 2016 compared to $3.5 million for the three months ended June 30, 2015. The

decrease in royalty revenue was due to the $3.5 million of back-owed royalties recognized in the three months ended June 30, 2015.

Cost of revenue, gross profit and gross margin. Cost of revenue was $13.3 million for the three months ended June 30, 2016 compared to $11.4 million for the three months ended June 30, 2015, an increase of $1.9 million or 17%. The increase was due primarily to an increase in production and personnel costs associated with the increase in product revenue, partially offset by vertical integration and other cost saving initiatives. Gross profit was $6.0 million for the three months ended June 30, 2016 compared to $7.8 million for the three months ended June 30, 2015, a decrease of $1.8 million or 23%. Gross margin decreased 1000 basis points to 31% for the three months ended June 30, 2016 from 41% for the three months ended June 30, 2015. This decrease in gross margin was driven primarily by a decrease in royalty revenue and an increase in the cost of unused product as a result of cancelled sales orders, which was partially offset by higher product revenue, vertical integration and other cost saving initiatives.

Sales and marketing. Sales and marketing expense was $10.6 million for the three months ended June 30, 2016 compared to $9.0 million for the three months ended June 30, 2015, an increase of $1.6 million or 18%. The increase was due primarily to a $1.3 million increase in sales commissions as a result of the increase in product revenue, and a $0.3 million increase in other sales and marketing related expenses. Sales and marketing expense increased as a percentage of total revenue to 55% for the three months ended June 30, 2016 from 47% for the three months ended June 30, 2015.

Beginning with the second quarter of 2016, the cost of unused product as a result of cancelled sales orders is included in cost of revenue. The cost of such unused product was previously included in sales and marketing expense. The unused product as a result of cancelled soles orders was $1.2 million and $0.7 million for the three months ended June 30, 2016 and 2015, respectively.

Research and development. Research and development expense was $4.0 million for the three months ended June 30, 2016 compared to $4.3 million for the three months ended June 30, 2015, a decrease of $0.3 million or 8%. The decrease was due primarily to a $0.3 million decrease in personnel costs compared to the previous three months ended June 30, 2015. Research and development expense decreased as a percentage of total revenue to 21% for the three months ended June 30, 2016 from 22% for the three months ended June 30, 2015.

General and administrative. General and administrative expense was $5.5 million for the three months ended June 30, 2016 compared to $5.4 million for the three months ended June 30, 2015, an increase of $0.1 million or 2%. The increase was due primarily to a $0.9 million increase in legal expenses related to litigation and other legal expenses and an increase of $0.2 million in director and officers insurance, offset by a $0.6 million decrease in personnel costs, a $0.3 million decrease in facility costs and a $0.1 million decrease in consulting fees. General and administrative expense remained the same as a percentage of total revenue at 28% for the three months ended June 30, 2016 and 2015.

Other income/(expense), net. Other income/(expense), net was $68,000 for the three months ended June 30, 2016 compared to $(9,000) for the three months ended June 30, 2015, an increase of $77,000, or 856%. The change was primarily due to a decrease in interest expense as a result of paying off long-term debt and an increase in interest income as a result of an increase in investments.

Income taxes. Income tax provision was $9,000 and $11,000 for the three months ended June 30, 2016 and 2015, respectively. 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 six months ended June 30, 2016 and 2015

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

Six Months Ended June 30,	2016 Amount	2016 As a% of Total Revenue	2015 Amount	2015 As a% of Total Revenue	2016 vs 2015 $ Change	2016 vs 2015 % Change
Revenue						
Product revenue	$39,086	99 %	$30,463	90 %	$8,623	28 %
Royalty	497	1	3,459	10	(2,962)	(86)
Total revenue	39,583	100	33,922	100	5,661	17
Cost of revenue	26,919	68	21,239	63	5,680	27
Gross profit	12,664	32	12,683	37	(19)	—
Operating expenses:						
Sales and marketing	21,762	55	18,151	54	3,611	20
Research and development	8,375	21	8,333	25	42	1
General and administrative	11,782	30	11,134	33	648	6
Total operating expenses	41,919	106	37,618	111	4,301	11
Loss from operations	(29,255)	(74)	(24,935)	(74)	(4,320)	(17)
Total other income/(expenses), net	182	—	(193)	(1)	375	194
Loss before income taxes	(29,073)	(73)	(25,128)	(74)	(3,945)	(16)
Income tax provision	13	—	21	—	(8)	(38)
Net loss	$(29,086)	(73)%	$(25,149)	(74)%	$(3,937)	(16)%

Product revenue. Product revenue was $39.1 million for the six months ended June 30, 2016 compared to $30.5 million for the six months ended June 30, 2015, an increase of $8.6 million or 28%, due principally to increased sales of our primary total knee products, iTotal CR and iTotal PS.

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):

Six Months Ended June 30,	2016 Amount	2016 As a % of Product Revenue	2015 Amount	2015 As a % of Product Revenue	2016 vs 2015 $ Change	2016 vs 2015 % Change
United States	$29,709	76 %	$22,130	73 %	$7,579	34 %
Germany	8,372	21	7,513	25	$859	11
Rest of world	1,005	3	820	2	185	23
Product revenue	$39,086	100 %	$30,463	100 %	$8,623	28 %

Product revenue in the United States was generated through our direct sales force and independent sales representatives. Product revenue outside the United States was generated through our direct sales force and distributors. The percentage of product revenue generated in the United States was 76% for the six months ended June 30, 2016 compared to 73% for the six months ended June 30, 2015. We believe the lower level of revenue as a percentage of product revenue outside the United States in the six months ended June 30, 2016 was due to the introduction of the iTotal PS in the United States, and partly due to the decline in exchange rates for Germany and the

United Kingdom.

Royalty revenue. 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 the same time we also entered into a worldwide license agreement with MicroPort for a lump-sum payment by MicroPort to us upon entering into the agreement. Royalty revenue related to these agreements was $0.5 million for the six months

ended June 30, 2016 compared to $3.5 million for the six months ended June 30, 2015. The decrease in royalty revenue was due to the $3.5 million of back-owed royalties recognized in the three months ended June 30, 2015.

Cost of revenue, gross profit and gross margin. Cost of revenue was $26.9 million for the six months ended June 30, 2016 compared to $21.2 million for the six months ended June 30, 2015, an increase of $5.7 million or 27%. The increase was due primarily to an increase in production and personnel costs associated with the increase in product revenue. Gross profit increased by $0.0 million or 0%, to $12.7 million for the six months ended June 30, 2016 compared to $12.7 million for the six months ended June 30, 2015, due to higher product revenue offset by the decrease in royalty revenue. Gross margin decreased -500 basis points to 32% for the six months ended June 30, 2016 from 37% for the six months ended June 30, 2015. This decrease in gross margin was driven primarily by lower royalty revenue during the year and higher cost of unused product as a result of cancelled sales orders, which was partially offset by the increase in product revenue, vertical integration and other cost saving initiatives.

Sales and marketing. Sales and marketing expense was $21.8 million for the six months ended June 30, 2016 compared to $18.2 million for the six months ended June 30, 2015, an increase of $3.6 million or 20%. The increase was due primarily to a $3.1 million increase in sales commissions as a result of the increase in product revenue, and a $0.5 million increase in other sales and marketing related expenses. Sales and marketing expense increased as a percentage of total revenue to 55% for the six months ended June 30, 2016 from 54% for the six months ended June 30, 2015.

Beginning with the second quarter of 2016, the cost of unused product as a result of cancelled sales orders is included in cost of revenue. The cost of such unused product was previously included in sales and marketing expense. The unused product as a result of cancelled sales orders was$1.6 million and $1.2 million for the six months ended June 30, 2016 and 2015, respectively.

Research and development. Research and development expense was $8.4 million for the six months ended June 30, 2016 compared to $8.3 million for the six months ended June 30, 2015, an increase of $42,000 or 1%. Research and development expense decreased as a percentage of total revenue to 21% for the six months ended June 30, 2016 from 25% for the six months ended June 30, 2015.

General and administrative. General and administrative expense was $11.8 million for the six months ended June 30, 2016 compared to $11.1 million for the six months ended June 30, 2015, an increase of $0.6 million or 6%. The increase was due primarily to a $1.8 million increase in legal costs related to litigation and other legal expenses, and an increase of $0.5 million in director and officers insurance, offset by a $0.5 million decrease in personnel costs, a $0.5 million decrease in freight costs, a $0.4 million decrease in facility costs, and a $0.3 million decrease in medical device tax. General and administrative expense decreased as a percentage of total revenue to 30% for the six months ended June 30, 2016 from 33% for the six months ended June 30, 2015.

Other income/(expense), net. Other income/(expense), net was $0.2 million for the six months ended June 30, 2016 compared to $(0.2) million for the six months ended June 30, 2015, an increase of $0.4 million, or 194%. The increase was primarily due to a decrease in interest expense as a result of paying off long-term debt and an increase in interest income as a result of an increase in investments.

Income taxes. Income tax provision was approximately $13,000 and $21,000 for the six months ended June 30, 2016 and 2015, respectively. 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.

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Liquidity, capital resources and plan of operations

Sources of liquidity and funding requirements

From our inception in June 2004 through the six months ended June 30, 2016, we have financed our operations through private placements of preferred stock, our initial public offering, or 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 June 30, 2016, we had an accumulated deficit of $354 million.

On July 7, 2015, we closed our 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. 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.

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 $0.3 million was outstanding as of June 30, 2016 and $0.5 million was outstanding as of December 31, 2015. We are scheduled to make monthly interest and principal payments for the MDFA facility through July 2017.

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;
- pursuing and maintaining appropriate regulatory clearances and approvals for our existing products and any new products that we may develop; 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. 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. We may not be able to obtain additional financing on terms favorable to us, or at all. 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 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.

As of June 30, 2016, we had cash and cash equivalents and and short-term and long-term investments of $87.6 million and $0.3 million in restricted cash allocated to lease deposits. Based on our current operating plan, we expect that our existing cash and cash equivalents and investments as of June 30, 2016 and anticipated revenue from operations, including from projected sales of our products, will enable us to fund our operating expenses and capital expenditure requirements 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):

	Six Months Ended June 30,			
	2016	2015	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$(27,001)	$(21,418)	$(5,583)	(26)%
Investing activities	(53,751)	(2,868)	(50,883)	(1,774)
Financing activities	1,514	668	846	127
Effect of exchange rate on cash	(134)	214	(348)	(163)
Total	$(79,372)	$(23,404)	$(55,968)	(239)%

Net cash used in operating activities. Net cash used in operating activities was $27.0 million for the six months ended June 30, 2016 and $21.4 million for the six months ended June 30, 2015, an increase of $5.6 million. These amounts primarily reflect net loss of $29.1 million for the six months ended June 30, 2016 and $25.1 million for the six months ended June 30, 2015. The net cash used in operating activities for the six months ended June 30, 2016 was affected by changes in our operating assets and liabilities, including $7.4 million related to accounts payable and accrued liabilities, $5.2 million related to deferred royalty revenue, a decrease of $4.5 million related to deferred initial public offering costs, an increase of $0.9 million in prepaid expenses, $3.7 million related to accounts receivable, $1.2 million related to inventory, as well as an increase of $0.3 million in stock compensation expense, and an increase of $0.3 million in depreciation expense.

Net cash used in investing activities. Net cash used in investing activities was $53.8 million for the six months ended June 30, 2016 and $2.9 million for the six months ended June 30, 2015, an increase of $50.9 million. These amounts primarily reflect an increase in investments of $55.4 million as well as an increase in costs related to the acquisition of property, plant, and equipment of $1.2 million, offset by an increase from the release of restricted cash of $0.2 million.

Net cash provided by financing activities. Net cash provided by financing activities was $1.5 million for the six months ended June 30, 2016 and $0.7 million for the six months ended June 30, 2015, an increase of $0.8 million. The increase was due to an increase in net proceeds from the exercise of common stock options of $0.9 million offset by a decrease in proceeds from the exercise of preferred stock warrants of $0.4 million.

Contractual obligations and commitments

During the six months ended June 30, 2016, there were no material changes to our contractual obligations and commitments described under Management’s Discussion and Analysis of Financial Condition and Results of

Operations in our Annual Report filed on Form 10-K for the year ended December 31, 2015.

Off-balance sheet arrangements

Through June 30, 2016, 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 as of 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 our Annual Report on Form 10-K for the year ended December 31, 2015 and Note B to the consolidated financial statements appearing in this Quarterly Report on Form 10-Q.

Recent accounting pronouncements
Information with respect to recent accounting developments is provided in Note B to the consolidated financial statements appearing in this Quarterly Report on Form 10-Q.

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 and investments.

Interest rate risk

We are exposed to limited market risk related to fluctuation in interest rates and market prices. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of June 30, 2016, we had cash and cash equivalents of $37.8 million consisting of demand deposits and money market accounts on deposit with certain financial institutions and $49.8 million in investments consisting of a variety of securities of high credit quality including U.S. treasury bonds, corporate bonds, commercial paper and agency bonds. The primary objective of our investment activities is to preserve our capital to fund our operations. Our investments may be subject to interest rate risk and could fall in value. However, because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant. Additionally, we had $9.1 million as of June 30, 2016 and $2.1 million as of December 31, 2015 held in foreign bank accounts that were not federally insured. 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 24% of our product revenue for the six months ended June 30, 2016 and 27% of our product revenue for the six months ended June 30, 2015 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 relating to fluctuations in currency rates. A 10% increase or decrease in foreign currency exchange rates would have resulted in additional income or expense of $0.2 million for the six months ended June 30, 2016 and 2015.

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 June 30, 2016. 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 June 30, 2016, 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 quarter ended June 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 purported securities class action lawsuit was filed against us, our chief executive officer, and chief financial officer in the United States District Court for the District of Massachusetts. The complaint was brought on behalf of an alleged class of those 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. On January 11, 2016, a consolidated amended complaint was filed purporting to allege claims arising 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 the defendants 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. The complaint sought, among other relief, certification of the class, unspecified compensatory damages, interest, attorneys' fees, expert fees and other costs. On March 18 2016, we filed a motion to dismiss all of the claims of the consolidated amended complaint. On August 3, 2016, the court granted our motion to dismiss in its entirety, denied the plaintiffs' request to replead their allegations, and dismissed the lawsuit. We do not know at this time whether the plaintiffs will appeal the court's decision, and there can be no assurance that we would be successful either in an appeal proceeding, or, if such a proceeding ends adversely to us, in any subsequent court proceeding. An adverse outcome 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 February 29, 2016, we filed a lawsuit against Smith & Nephew, Inc. ("Smith & Nephew") in the United States District Court for the District of Massachusetts Eastern Division, which we amended on June 13, 2016. The lawsuit alleges that Smith & Nephew's Visionaire® patient-specific instrumentation as well as the implants systems used in conjunction with the Visionaire instrumentation infringe nine of our patents, and it requests, among other relief, monetary damages for willful infringement, enhanced damages and a permanent injunction.

On May 27, 2016, Smith & Nephew filed an Answer and Counterclaims in response to our lawsuit, which it subsequently amended on July 22, 2016. Smith & Nephew denied that its Visionaire® patient-specific instrumentation as well as the implants systems used in conjunction with the Visionaire instrumentation infringe the patents asserted by us in the lawsuit. It also alleged two affirmative defenses: that our asserted patents are invalid and that we are barred from relief under the doctrine of laches. In addition, Smith & Nephew asserted a series of counterclaims, including counterclaims seeking declaratory judgments that Smith & Nephew's accused products do not infringe our patents and that our patents are invalid. Smith & Nephew also alleged that ConforMIS infringes ten patents owned or exclusively licensed by Smith & Nephew: two patents that Smith & Nephew alleges are infringed by our iUni and iDuo products; three patents that Smith & Nephew alleges are infringed by our iTotal products; and five patents that Smith & Nephew licenses from Kinamed, Inc. of Camarillo, California and that it alleges are infringed by our iUni, iDuo and iTotal products. Due to Smith & Nephew's licensing arrangement with Kinamed, Kinamed has been named as a party to the lawsuit. Smith & Nephew and Kinamed have requested, among other relief, monetary damages for willful infringement, enhanced damages and a permanent injunction. An adverse outcome of this 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.

ITEM 1A. RISK FACTORS

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 1 of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks related to our financial position

We have incurred losses in the past, expect to incur losses for at least the next several years and may never achieve profitability.

We have incurred significant net operating losses in every year since our inception and expect to incur net operating losses for the next several years. Our net loss was $29 million for the six months ended June 30, 2016 and $25 million for the six months ended June 30, 2015. As of June 30, 2016, we had an accumulated deficit of $354 million. We expect to continue to incur significant product development, clinical and regulatory, sales and marketing, manufacturing and other expenses as our business continues to grow and we expand our product offerings. Additionally, our general and administrative expense will continue to increase due to the additional operational and reporting costs associated with our expanded operations and being a public company. 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. In addition, our growth may slow, for reasons described in these risk factors. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations.

We expect to incur substantial expenditures in the foreseeable future and might require additional capital to support business growth. This capital might not be available on terms favorable to us or at all.

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;
- pursuing and maintaining appropriate regulatory clearances and approvals for our existing products and any new products that we may develop; 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 continue to 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 will be revenue generated from the sales of our products and revenues that we may generate in connection with licensing our intellectual property. In November 2014, we borrowed the first of two $10 million term loans , referred to as the SVB/Oxford Term Loan A, under a loan and security agreement with Silicon Valley Bank, or SVB, and Oxford Finance, LLC, or the 2014 Secured Loan Agreement. In September 2015, we voluntarily prepaid the SVB/Oxford Term Loan A in full and terminated our right to draw down the term loans and any security interest in favor of Oxford Finance, LLC. In December 2015, we also terminated a revolving line of credit we had from SVB.

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. 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 equity or debt financings to secure additional funds. We may not be able to obtain additional financing on terms favorable to us, or at all. To the extent that we raise additional capital through the

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future sale of equity or convertible 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 agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures.

Risks related to our business, industry and competitive position

We have a limited operating history and may face difficulties encountered by early stage companies in rapidly evolving markets.

We began operations in 2004, introduced our first product commercially in 2007 and only introduced our best-selling product, our iTotal CR, in 2011. Accordingly, we have a limited operating history upon which to base an evaluation of our business and prospects. In assessing our prospects, you must consider the risks and difficulties frequently encountered by early stage companies in new and rapidly evolving markets, particularly companies engaged in the development and sales of medical devices. These risks include our ability to:

- manage rapidly changing and expanding operations;
- establish and increase awareness of our brand and strengthen customer loyalty;
- restore and expand physician relationships after disruptions in supply or delays in delivery of our products;
- grow our direct sales force and increase the number of our independent sales representatives and distributors to expand sales of our products in the United States and in targeted international markets;
- implement and successfully execute our business and marketing strategy;
- respond effectively to competitive pressures, responses and developments;
- continue to develop and enhance our products and products in development;
- obtain regulatory clearance or approval to commercialize new products and enhance our existing products;
- expand our presence in international markets;
- perform clinical and economic research and studies on our existing products and current and future product candidates; and
- attract, retain and motivate qualified personnel.

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. We can also be negatively affected by general economic conditions. Because of our limited operating history, we may not have insight into trends that could emerge and negatively affect our business. As a result of these or other risks, our business strategy might not be successful.

We have derived nearly all of our revenues from sales of a limited portfolio of knee replacement products and may not be able to maintain or increase revenues from these products. A substantial portion of our revenues are derived from a small number of customers.

To date, we have derived nearly all of our revenues from sales of our knee replacement products, and we expect that sales of these products will continue to account for the majority of our revenues for at least the next several years. If we are unable to achieve and maintain significantly greater market acceptance of these products, we may be materially constrained in our ability to fund our operations and the development and commercialization of improvements and other products. Any factors that negatively impact sales or growth in sales of our current products, including the size of the addressable markets for these products, our failure to convince surgeons to adopt our products, competitive factors and other factors described in these risk factors, could adversely affect our business, financial condition and operating results.

In addition, as part of our commercial strategy we work to significantly increases our sales in targeted markets by focusing on high-volume, influential surgeons who use our products. As a result, orders from a relatively small number of surgeons provide a significant portion of our total revenue. The loss of, or significant curtailment of orders by, one or more of our high-volume doctors, including curtailments due to reduced

reimbursement rates, adoption of our competitors' products or the timing of orders by these doctors, may adversely affect our results of operations and financial condition.

We may not be successful in the development of, obtaining regulatory clearance for, or commercialization of, additional products.

We are expanding our offerings to include an additional joint replacement product for the knee, the iTotal PS, which we launched commercially, and are developing our first hip replacement product, the iTotal Hip. We initially filed for marketing clearance of the iTotal Hip in 2015 with the FDA; however, after consultation with the FDA, we elected to withdraw the application and intend to submit a new application for 510(k) clearance of iTotal Hip in the second half of 2016. However, we may not be able to successfully commercialize the iTotal PS and we may not be able to develop or obtain regulatory approval or clearance of or successfully commercialize the iTotal Hip. Any factors that delay the commercial launch of, including the process for obtaining regulatory clearance for, our additional products, or result in sales of our additional products increasing at a lower rate than expected, could adversely affect our business, financial condition and operation results. In addition, even if we do launch these products, there can be no assurance that these products will be accepted in the market or commercially successful or profitable.

All of the products we currently market in the United States have either received pre-market clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, or are exempt from pre-market review. The FDA's 510(k) clearance process requires us to show that our proposed product is "substantially equivalent" to another legally marketed product that did not require premarket approval. This process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes and does not always require clinical studies. To date, we have not been required to conduct clinical studies or obtain clinical data in order to obtain regulatory clearance in the United States for our products. Additionally, to date, we have not been required to complete clinical studies in connection with obtaining regulatory clearance for the sale of our products outside the United States. If we must conduct clinical studies or obtain clinical data to obtain regulatory clearance or approval for any of our products in the United States or elsewhere. The results of such studies may not be sufficient to support regulatory clearance or approval. In addition, our costs of developing and the time to develop our products would increase significantly. Moreover, even if we obtain regulatory clearance or approval to market a product, the FDA, in the United States, or a Notified Body, in the EU, has the power to require us to conduct postmarketing studies beyond those we contemplate conducting. We may need to raise additional funds to support any such clinical efforts, and if we are required to conduct such clinical efforts, our results of operations would be adversely affected.

We are in a highly competitive market and face competition from large, well-established companies as well as new market entrants.

The market for orthopedic replacement products generally, and for knee and hip implant products in particular, is intensely competitive, subject to rapid change and dominated by a small number of large companies. Our principal competitors are the major producers of prosthetic knee and hip replacement products. We also compete with numerous smaller companies, many of whom have a significant regional market presence. In addition, a number of companies are developing biologic cartilage repair solutions to address osteoarthritis of the knee that could reduce the demand for knee replacement procedures and products. Stem cell therapies and other new, emerging therapies could reduce or obviate the need for joint replacement surgery in the future.

Many of our larger competitors are either publicly traded or divisions or subsidiaries of publicly traded companies, and enjoy several competitive advantages over us, including:

- greater financial resources, cash flow, capital markets access and other resources for product research and development, sales and marketing and litigation;
- significantly greater name recognition;
- established relations with, in some cases over decades, orthopedic surgeons, hospitals and other medical facilities and third-party payors;
- established products that are more widely accepted by, a greater number of orthopedic surgeons, hospitals and other medical facilities and third-party payors;
- more complete lines of products for knee or other joint replacements;
- larger and more well-established distribution networks with significant international presence;

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- products supported by long-term clinical data and long-term product survivorship data;
- greater experience in obtaining and maintaining FDA and other regulatory approvals or clearances for products and product enhancements; and
- more expansive portfolios of intellectual property rights and greater funds available to engage in legal action.

As a result of these advantages, our competitors may be able to develop, obtain regulatory clearance or approval for and commercialize products and technologies more quickly than us, which could impair our ability to compete. If alternative treatments are, or are perceived to be, superior to our products, or if we are unable to increase market acceptance of our products, as compared to existing or competitive products, sales of our products could be negatively affected and our results of operations could suffer. Our competitors also may seek to copy our products using similar technologies for use in other joints or applications into which we have not yet expanded, which would have the effect of reducing the market potential of our current or future products. In addition, based on their favorable attributes, we expect our products to be offered at higher price points than some competitive products, and our pricing decisions may make our products less competitive.

We are deploying a new business model in an effort to disrupt a relatively mature industry. In order to become profitable, we will need to scale this business model considerably through increased sales.

Our business model, based on our iFit Image-to-Implant technology platform and our just-in-time delivery is new to the joint replacement industry. We manufacture our customized replacement implants and iJigs to order and do not maintain significant inventory of finished product. We deliver the customized replacement implants and iJigs to the hospital days in advance of the scheduled arthroplasty procedure. In order to deliver our product on a timely basis, we must execute our processes on a defined schedule with limited room for error. Our competitors generally sell from a pre-produced inventory and can sell products and satisfy demand without being as dependent on business continuity. Even minor delays or interruptions to our design, manufacturing or delivery processes could result in delays in our ability to deliver products to specification, or at all, thereby significantly impacting our reputation and our ability to make commercial sales. In order to become profitable, we will need to significantly increase sales of our existing products and successfully develop and commercially launch future products at a scale that we have not yet achieved. In order to increase our gross margins we will need, among other things, to:

- increase sales of our products;
- negotiate more favorable prices for the materials we use to manufacture our products;
- negotiate more favorable prices for the manufacture of certain components of our products that are manufactured for us by third parties;
- deploy new versions of our software that reduce the costs associated with the design of our products; and
- expand our internal manufacturing capabilities to manufacture certain components of our products at a lower unit cost than vendors we currently use.

However, we may not be successful in achieving these objectives, and our gross margins may not increase, or could even decrease. We may not be successful in executing on our business model, in increasing our gross margins or in bringing our sales and production up to a scale that will be profitable, which would have a material adverse effect on our financial condition, results of operations and cash flows.

To be commercially successful, we must convince orthopedic surgeons that our joint replacement products are attractive alternatives to our competitors' products.

Orthopedic surgeons play a significant role in determining the course of treatment and, ultimately, the type of product that will be used to treat a patient. Acceptance of our products depends on educating orthopedic surgeons as to the distinctive characteristics, perceived clinical benefits, safety and cost-effectiveness of our products as compared to our competitors' products. If we are not successful in convincing orthopedic surgeons of the merits of our products or educating them on the use of our products, they may not use our products and we will be unable to increase our sales or reach profitability.

We believe orthopedic surgeons will not widely adopt our products unless they determine, based on experience, clinical data and published peer-reviewed journal articles, that our products and the techniques to implant them provide benefits to patients and are attractive alternatives to our competitors' products. Surgeons may be hesitant to change their medical treatment practices for the following reasons, among others:

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- comfort and experience with competitive products;
- perceived differences in surgical technique;
- existing relationships with competitors, competitive sales representatives and competitive distributors;
- lack or perceived lack of evidence supporting additional patient benefits from use of our products compared to competitive products, especially products that may claim to be "customized," "patient-specific," "personalized" or "individually-made";
- perceived convenience of using products from a more complete line of products than we offer, including as a result of our lack of a joint revision system;
- perceived liability risks generally associated with the use of new products and procedures, including the lack of long-term clinical data;
- perceived risks of failure of timely delivery as a result of our "just in time" manufacturing and delivery model
- damage to our reputation as a result of our recent voluntary recall;
- unwillingness to wait for the implants to be delivered;
- unwillingness to submit patients to computed tomography, or CT, scans;
- higher cost or perceived higher cost of our products compared to competitive products; and
- the additional time commitment that may be required for training.

If clinical, functional or economic data does not demonstrate the benefits of using our products, surgeons may not use our products. In such circumstances, we may not achieve expected sales and may be unable to achieve profitability.

To understand the clinical, functional and economic benefits of using our products, surgeons may refer to published studies sponsored by us, conducted by orthopedic surgeons who are paid consultants to us or conducted independently by orthopedic surgeons comparing our customized products to off-the-shelf products. To the extent such studies do not report favorably on our products, surgeons may be less likely to use our products. We are aware of one such clinical study conducted by a single surgeon and involving only 21 iTotal CR patients, in which our iTotal CR product performed less well than off-the-shelf knee replacement products. This study compared our iTotal CR product to posterior-stabilized and non-cemented rotating platform implants, which we believe makes the comparison of questionable value. The measures on which our iTotal CR product performed less well than the off-the-shelf products were range of motion at six weeks (although our iTotal CR product performed equally well at minimum one year follow-up) and manipulation under anesthesia, or MUA, a procedure used post-operatively to adjust a knee replacement implant to improve its function. In a subsequent multi-center study of our iTotal CR product involving 357 patients for which we provided financial support, the 3.1% rate of MUA for our iTotal CR product was substantially lower than the 28.6% rate of MUA shown in this earlier and much smaller single-surgeon study. By comparison, the rate of MUA reported in a separate study of off-the-shelf implants was 4.6%.

Moreover, overall patient satisfaction with our products, as observed by individual surgeons, will continue to be an important factor in surgeons' deciding to use our products for joint replacement procedures. The success of any particular joint replacement procedure, and a patient's satisfaction with the procedure, is dependent on the technique and execution of the procedure by the surgeon. Even if our iJigs and implants are manufactured exactly to specification, there is a risk that the surgeon makes a mistake during a procedure, leading to patient dissatisfaction with the procedure. In addition, following joint replacement procedures, fibrosis, scarring and other issues unrelated to the choice of implant product can lead to patient dissatisfaction. Furthermore, based on their prior experience using non-customized, off-the-shelf implant products, surgeons may be accustomed to making modifications to the implant components during a procedure. Because our products are already individually-made to fit the unique anatomy of each patient, modifications made to the implant components or the process of fitting the implant during the surgical procedure are not recommended and may result in negative surgical outcomes. If patients do not have a good outcome following procedures conducted using our products, surgeons' views of our products may be negatively impacted.

The first step in the process for a patient to receive one of our joint replacement products involves a CT scan of the patient's affected joint and one or two CT images of other biomechanically relevant joints. CT scans involve the use of radiation to image the bone and other tissue in the scanned joint. Surgeons may be reluctant to recommend, and patients may be reluctant to undertake, a procedure that involves this imaging modality as a result of the actual or perceived risks of exposure to radiation as part of the CT scan. The use of an off-the-shelf joint replacement product

generally does not require a CT scan. As a result, surgeons and patients may view the

alternative joint replacement approaches that do not require a CT scan as more attractive. Competitors may promote their products on this basis, and as a result, our sales, revenue and profitability may be adversely affected.

Surgeons, hospitals and independent sales representatives and distributors may have existing or future relationships with other medical device companies that make it difficult for us to establish new or continued relationships with them; as a result, we may not be able to sell and market our products effectively.

We believe that to sell and market our products effectively, we must establish relationships with key surgeons and hospitals and other medical facilities in the field of orthopedic surgery. Many of these key surgeons and hospitals and other medical facilities already have long-standing relationships with large, well-known companies that dominate the medical devices industry. Some of these relationships may be contractual, such as collaborative research programs or consulting relationships. Because of these existing relationships, surgeons and hospitals and other medical facilities may be reluctant or unable to adopt our products to the extent our products compete with, or have the potential to compete with, products supported by these existing relationships. Even if these surgeons and hospitals and other medical facilities purchase our products, they may be unwilling to provide us with follow up clinical and economic data important to our efforts to distinguish our products.

We also work with independent sales representatives and distributors to market, sell and support our products in the United States and international markets. If our independent sales representatives and distributors believe that a relationship with us is less beneficial than other relationships they may have with more established or well-known medical device companies, they may be unwilling to establish or continue their relationships with us, making it more difficult for us to sell and market our products effectively.

The success of our products is dependent on our ability to demonstrate their clinical benefits.

To date, we have collected only limited clinical data supporting the favorable attributes of our iUni, iDuo and iTotal CR knee replacement products and no clinical data regarding our iTotal PS knee replacement product or iTotal Hip replacement product, which is currently in development. Our ongoing or future clinical studies may not yield the results that we expect to obtain and may not demonstrate that our products are superior to, or may demonstrate that our products are inferior to, off-the-shelf products with regard to clinical, functional or economic measures. Long-term device survivorship data for our products may show that the survivorship of our customized joint replacement products is shorter than that of off-the-shelf products. Competitors may initiate their own clinical studies which may yield data that is inconsistent with data from our studies or data showing the superiority of their products over our products.

The safety and efficacy of our products is supported by limited short- and long-term clinical data, and our products might therefore prove to be less safe and effective than initially thought.

To date, we have obtained regulatory clearance for our products in the United States without conducting premarket clinical studies, and we do not believe that we will need premarket clinical data in order to obtain regulatory clearance in the United States for additional knee products or iTotal Hip. Additionally, to date, we have not been required to complete premarket clinical studies in connection with obtaining regulatory approval for the sale of our products outside the United States, and we do not believe that we will need premarket clinical data in order to obtain regulatory clearance in most jurisdictions outside the United States for additional knee products or iTotal Hip. However, to date, the regulatory agencies in the EU have required us to perform post-market clinical studies on our cleared products and may continue to do so with respect to our future products. As a result of the absence of premarket clinical studies, we currently lack the breadth of published long-term clinical data supporting the safety and efficacy of our products and the benefits they offer that might have been generated in connection with other approval processes. For these reasons, orthopedic surgeons may be slow to adopt our products, we may not have comparative data that our competitors have or are generating and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would slow the adoption of our products by orthopedic surgeons, reduce our ability to achieve expected sales and could prevent us from achieving or sustaining profitability. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, suspension or withdrawal of FDA clearance or approval, loss of our ability to CE Mark our products, significant legal liability or harm to our business reputation.

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If we are unable to continue to develop new products and technologies in a timely manner, or if we develop new products and technologies that are not accepted by the market, the demand for our products may decrease or our products could become obsolete, and our revenue and profitability may decline.

We are continually engaged in product development, research and improvement efforts. Our ability to grow sales depends on our capacity to keep up with existing or new products and technologies in the joint replacement product markets. If our competitors are able to develop and introduce new products and technologies before us, they may gain a competitive advantage and render our products and technologies obsolete. The additional markets into which we plan to expand our business are subject to similar competitive pressures and our ability to successfully compete in those markets will depend on our ability to develop and market new products and technologies in a timely manner, and in particular, on our ability to successfully commercially launch our new iTotal PS knee replacement product and complete development of, obtain regulatory clearance for and successfully commercially launch our planned iTotal Hip replacement product.

We believe that offering a broad line of joint replacement products is important to convincing surgeons to use our products generally. If we do not complete development of and obtain regulatory clearance for our iTotal Hip, or if market acceptance of iTotal PS or iTotal Hip is less than we expect, the growth in sales of our existing products may slow and our financial results would be adversely affected. The success of our product development efforts will depend on many factors, including our ability to:

- create innovative product designs;
- accurately anticipate and meet customers' needs;
- commercialize new products in a timely manner;
- differentiate our offerings from competitors' offerings;
- achieve positive clinical outcomes with new products;
- demonstrate the safety and reliability of new products;
- satisfy the increased demands by healthcare payors, providers and patients for shorter hospital stays, faster post-operative recovery and lower-cost procedures;
- provide adequate medical education relating to new products; and
- manufacture and deliver implants and instrumentation in sufficient volumes on time.

Moreover, research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology or other innovation. Our competition may respond more quickly to new or emerging technologies, undertake more effective marketing campaigns, adopt more aggressive pricing policies, have greater financial, marketing and other resources than us or may be more successful in attracting potential customers, employees and strategic partners.

Even in the event that we are able successfully to develop new products and technologies, they may not produce revenue in excess of the costs of development and may be quickly rendered obsolete as a result of changing customer preferences, changing demographics, slowing industry growth rates, declines in the knee or other orthopedic replacement implant markets, evolving surgical philosophies, evolving industry standards or the introduction by our competitors of products embodying new technologies or features. New materials, product designs and surgical techniques that we develop may not be accepted quickly, in some or all markets, because of, among other factors, entrenched patterns of clinical practice, the need for regulatory clearance and uncertainty with respect to third-party reimbursement of procedures that utilize our products.

If surgeons, hospitals and other medical facilities are unable to obtain favorable reimbursement rates from third-party payors for procedures involving use of our products, if third-party payors adopt policies that preclude payment for the use of our products, or if reimbursement from third-party payors for such procedures significantly declines, surgeons, hospitals and other medical facilities may be reluctant to use our products and our sales may decline.

In the United States, surgeons and hospitals and other medical facilities who purchase medical devices such as our products generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to pay for all or a portion of the costs and fees associated with the joint replacement surgery and the products utilized in the procedure, including the cost of our products. Our customers' access to adequate coverage and reimbursement for the procedures performed using our products by government and third-party

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payors is central to the acceptance of our current and future products. Payors may view new products or products that have only recently been launched or with limited clinical data available, including the iTotal CR, iTotal PS and iTotal Hip, as investigational, unproven or experimental, and on that basis may deny coverage of procedures involving use of our products. For example, we are aware of certain private insurers that at this time consider the use of custom implants or patient-specific instrumentation for knee replacement surgery as investigational, unproven or experimental. In addition, the American Academy of Orthopedic Surgeons currently does not recommend using patient-specific instrumentation. We may be unable to sell our products on a profitable basis if government and third-party payors deny coverage for such procedures or set reimbursement rates at unfavorable levels for procedures involving use of our products. Further, if hospitals participating in the new Medicare CJR program do not use our products in the volumes we anticipate, it may have an adverse impact on our sales going forward.

To contain costs of new technologies, governmental healthcare programs and third-party payors are increasingly scrutinizing new and even existing treatments by requiring extensive evidence of favorable clinical outcomes and cost effectiveness. Surgeons, hospitals and other medical facilities may not purchase our products if they do not receive satisfactory reimbursement from these third-party payors for the cost of the procedures using our products. Payors continue to review their coverage policies carefully, and to implement new policies, for existing and new therapies and can, without notice, deny coverage for treatments that include the use of our products. If third-party payors refuse coverage for these procedures or if we are not able to be reimbursed at cost-effective levels, this could have a material adverse effect on our business and operations.

The first step in the process for a patient to receive one of our joint replacement products involves a CT scan of the patient's affected joint and one or two CT images of other biomechanically relevant joints. The cost of the CT scan is not always reimbursed by third-party payors. In addition, the costs of alternative imaging techniques that we could substitute for a CT scan in our iFit process, such as magnetic resonance imaging, or MRI, generally, are higher than the cost of a CT scan. If third-party payors do not reimburse the costs of the CT scan or any alternative imaging technique, we could find that we have to pay these costs ourselves, or reduce the prices of our products that we charge hospitals and other medical facilities that bear these costs, in order to maintain market acceptance of our products. In such event, our costs of sales would increase and our profitability would be adversely affected.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 or, collectively, the PPACA, has changed how some healthcare providers are reimbursed by the Medicare program and some private third-party payors. As physicians consolidate into Accountable Care Organizations, or ACOs, these physicians, through the ACOs, are taking on the financial risk for providing care to all patients in their ACO. Medicare and some private third-party payors provide a set global, annual payment per beneficiary or member of the ACO. ACOs use these payments to provide care for their patients. When the cost of providing care is less than payments received, the ACO shares the savings with Medicare and the private third-party payors. ACOs are therefore incentivized to control and reduce the cost of patient care. Attempts to control and reduce the cost of care within an ACO could result in fewer referrals for elective surgery, or require the use of the least expensive implant available, either or both of which could cause our revenue to decline.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for orthopedic implants and procedures. Many countries use a system of Diagnosis Related Groups to set a price for a particular medical procedure, including orthopedic implants that will be used in that procedure. In the EU, the pricing of medical devices is subject to governmental control, and pricing negotiations with governmental authorities can take considerable time after a device has been CE marked. To obtain reimbursement or pricing approval in some countries, we may be required to supply data that compares the cost-effectiveness of our products to other available therapies. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended collection periods. Further, reimbursement rates for our products in other jurisdictions, including in Germany, where we have attained reimbursement rates at higher price points than some competitive products, could change negatively. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products outside of the United States, which would negatively affect the long-term growth of our business.

We are subject to cost-containment efforts of hospitals and other medical facilities and group purchasing organizations, which may have a material adverse effect on our financial condition, results of operations and cash flows.

In order for surgeons to use our products, the hospitals and other 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. In addition, many of our customers and potential customers are members of group purchasing organizations that are focused on containing costs. Group purchasing organizations negotiate pricing arrangements with medical supply and device manufacturers, and these negotiated prices are made available to a group purchasing organization's affiliated hospitals and other medical facilities. If we do not have pricing agreements with group purchasing organizations, their affiliated hospitals and other medical facilities may be less likely to purchase our products. Our failure to complete purchasing contracts with hospitals or other medical facilities or contracts with group purchasing organizations may cause us to lose market share to our competitors and could have a material adverse effect on our sales, financial condition, results of operations and cash flows. Our competitors may also elect to lower their prices in select accounts, thereby rendering our products non-competitive on the basis of price, with resulting losses in sales to these accounts.

If we are unable to train orthopedic surgeons on the safe and appropriate use of our products, we may be unable to achieve our expected growth.

An important part of our sales process includes training surgeons on the safe and appropriate use of our products. If we become unable to attract potential new surgeon customers to our training programs, or if we are unable to attract existing customers to training programs for future products, we may be unable to achieve our expected growth.

There is a learning process involved for orthopedic surgeons to become proficient in the use of our products. It is critical to the success of our commercialization efforts to train a sufficient number of orthopedic surgeons and to provide them with adequate instruction in the use of our products. This training process may take longer than expected and may therefore affect our ability to increase sales. Following completion of training, we rely on the trained surgeons to advocate the benefits of our products in the broader marketplace. Convincing surgeons to dedicate the time and energy necessary for adequate training of themselves or other surgeons is challenging, and we may not be successful in these efforts. If surgeons are not properly trained, they may misuse or ineffectively use our products. This may also result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could have an adverse effect on our business.

Although we believe our training methods for surgeons are conducted in compliance with FDA and other applicable regulations, if the FDA or other applicable government agency determines that our training constitutes promotion of an unapproved use or other inappropriate promotion, they could request that we modify our training or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalty.

We rely on our direct sales force to sell our products in targeted geographic regions and any failure to maintain our direct sales force could harm our business.

We rely on our direct sales force to market and sell our products in targeted geographic regions in the United States, Germany and the United Kingdom. We do not have any long-term employment contracts with the members of our direct sales force. The members of our direct sales force are highly trained and possess substantial technical expertise, and the loss of these personnel to competitors or otherwise could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement direct sales force personnel, our revenues and results of operations could be materially harmed.

If our relationships with independent sales representatives and distributors are not successful, our ability to market and sell our products would be harmed.

We depend on relationships with independent sales representatives and distributors of orthopedic implants and instrumentation for the marketing and sales of our products in geographic regions that are not targeted by our direct sales force, including parts of the United States, Switzerland, Hong Kong and Singapore. Revenues generated from the sales of our products by independent sales representatives represented approximately 66% of our total revenue from sales of our products in the United States for the six months ended June 30, 2016, and approximately 61% of our total revenue from sales of our products in the United States for the six months ended June 30, 2015. We did not generate any revenue from sales of our products by independent sales representatives outside the United States in the six months ended June 30, 2016 or 2015. Revenues generated from the sales of our products to distributors represented approximately 4% of our total revenue from sales of our products outside the United States for the six months ended June 30, 2016 and approximately 4% for the six months ended June 30, 2015. We did not generate any

revenue from sales of our products to distributors in the United States in the six

months ended June 30, 2016 or 2015. We have entered into agreements with these independent sales representatives and distributors; we have a limited ability, however, to influence the efforts of these independent sales representatives and distributors. Relying on independent sales representatives and distributors for our sales and marketing could harm our business for various reasons, including:

- agreements may terminate prematurely due to disagreements or may result in litigation;
- we may not be able to renew existing agreements on acceptable terms;
- our independent sales representatives and distributors may not devote sufficient resources to the sale of products;
- our independent sales representatives and distributors may be unsuccessful in marketing our products;
- our existing relationships with distributors may preclude us from entering into additional future arrangements with other distributors; and
- we may not be able to negotiate future agreements on acceptable terms or at all.

None of our independent sales representatives or distributors have been required to sell our products exclusively and many of them may freely sell the products of our competitors. We cannot be certain that they will prioritize selling our products over those of our competitors, and our competitors may enter into arrangements with our independent sales representatives and distributors that require them to cease distributing our products. If one or more of our independent sales representatives or any of our key distributors were to cease selling or distributing our products, our sales could be adversely affected. In such a situation, we may need to seek alternative relationships with independent sales representatives and distributors or increase our reliance on our other independent sales representatives or distributors or our direct sales force, which may not prevent our sales from being adversely affected. Additionally, to the extent that we enter into additional arrangements with independent sales representatives or distributors to perform sales, marketing or distribution services, the terms of the arrangements could cause our product margins to be lower than if we directly marketed and sold our products.

The current global economic uncertainties may adversely affect our results of operations.

Our results of operations could be substantially affected by global economic conditions and local operating and economic conditions, which can vary substantially by market. Although the U.S. economy continues to recover from the worst recession in decades, unemployment and consumer confidence have not rebounded as quickly as in some prior recessions, resulting in reduced numbers of insured patients and the deferral of some elective joint replacement procedures. Global economic conditions remain uncertain. Much of Europe remains in recession as the credit ratings of several European countries and the possibility that certain European Union member states will default on their debt obligations have contributed to significant uncertainty about the stability of global credit and financial markets. In addition, the Chinese economy has recently showed slowing growth, and economies of oil producing regions are weakening, in some cases rapidly and significantly as a result of volatility in the supply and price of oil. Challenges and pressures in the global economy may ultimately impact joint replacement procedure volumes, average selling prices and reimbursement rates from third-party payors, any of which could adversely affect our results of operations. Unfavorable economic conditions can depress sales in a given market and may result in actions that adversely affect our margins, constrain our operating flexibility or result in charges which are unusual or non-recurring. Certain macroeconomic events, such as the continuing adverse conditions in the global economy, the recent recessions in Europe, the Eurozone crisis and the softening Chinese economy could have a more wide-ranging and prolonged impact on the general business environment, which could also adversely affect us. These economic developments could affect us in numerous ways, many of which we cannot predict. Among the potential effects could be:

- an increase in our variable interest rates;
- an inability to access credit markets should we require external financing;
- a reduction in the purchasing power of our European Union customers due to a deterioration of the value of the euro;
- inventory issues due to financial difficulties experienced by our suppliers and customers, including distributors; and
- delays in collection.

In addition, it is possible that further deteriorating economic conditions, and resulting U.S. federal budgetary concerns, could prompt the U.S. federal government to make significant changes in the Medicare program, which could adversely affect our results of operations. We are unable to predict the likely duration and severity of the current disruption in financial markets and adverse economic conditions, or the effects these disruptions and conditions could have on us.

Economic uncertainty may reduce patient demand for knee or other joint replacement procedures. If there is not sufficient patient demand for the procedures for which our products are used, customer demand for our products would likely drop, and our business, financial condition and results of operations would be harmed.

The orthopedics industry in which we operate is vulnerable to economic trends. Joint replacement procedures are elective procedures, the cost of which may not be fully covered by or reimbursable through government, including Medicare or Medicaid, or private health insurance. In times of economic uncertainty or recession, individuals may reduce the amount of money that they spend on deferrable medical procedures, including joint replacement procedures. Economic downturns in the United States and international markets could have an adverse effect on demand for our products.

Our existing and any future indebtedness could adversely affect our ability to operate our business.

As of June 30, 2016, we had $334,000 of outstanding term loans under our credit facility with the Massachusetts Development Finance Agency, referred to as the MDFA facility. We anticipate paying off the remaining interest and principal under the MDFA facility by July 2017.

Our obligations under the MDFA facility will require us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes.

Our obligations under the MDFA facility and other agreements governing our indebtedness may be subject to potential acceleration upon the occurrence of specified events of default, including payment defaults or the occurrence of a material adverse change in our business, operations or financial or other condition. If an event of default occurs and the lenders accelerate the amounts due, we may not be able to make payments in the amount of obligations that were accelerated, and the lenders could seek to enforce security interests in the collateral securing such indebtedness. We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our current or future debt arrangements.

Our outstanding indebtedness combined with our other financial obligations and contractual commitments, including any additional indebtedness that we may incur, could increase our vulnerability to adverse changes in general economic, industry and market conditions; limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and place us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

Our inability to maintain adequate working relationships with external research and development consultants and surgeons could have a negative impact on our ability to market and sell new products.

We maintain professional working relationships with external research and development consultants and leading surgeons and medical personnel in hospitals and universities who assist in product research and development and training. We continue to emphasize the development of proprietary products and product improvements to complement and expand our existing product line. It is possible that U.S. federal and state laws requiring us to disclose payments or other transfers of value, such as free gifts or meals, to physicians and other healthcare providers could have a chilling effect on these relationships with individuals or entities that may, among other things, want to avoid public scrutiny of their financial relationships with us. In addition, consultants, surgeons and medical personnel in hospitals and universities may be subject to conflict of interest policies that limit our ability to engage these individuals as our advisors and in connection with future development and training efforts. If we are unable to establish and maintain our relationships with consultants, surgeons and medical personnel, our ability to develop and sell new and improved products could decrease, and our future operating results could be unfavorably affected.

Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile.
We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, business interruption insurance, property insurance and workers' compensation insurance. The cost of maintaining product liability insurance on implantable medical devices has increased substantially over the past few years and could continue to substantially increase, due to general market trends, as part of an evaluation of our specific loss history and other factors. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. Similarly, if we exhaust our current insurance coverage for any given policy period, we would be required to operate our business without indemnity from commercial insurance providers for any claims made that are attributable to that policy period.
Consolidation in the healthcare industry could lead to demands for price concessions or the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or operating results.
Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and likely will continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for some of our customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products and may adversely impact our business, financial condition or operating results.
Risks related to our manufacturing
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 completed the transfer of our manufacturing operations from the Burlington facility to our Wilmington facility in August 2015 and vacated the Burlington facility. 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. However, delays in validation of revised or new manufacturing processes or FDA clearance 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 products were manufactured and distributed from our Wilmington manufacturing facility between July 18, 2015 and August 28, 2015. We isolated the root cause to a step in our ethylene oxide sterilization process conducted by a vendor. We have since completed final testing and implemented corrective actions, and we 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, 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 orthopedic surgeons, 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.
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 improve internal efficiencies and to introduce new manufacturing processes, including vertical integration of the manufacturing process by performing more manufacturing in-house. 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;
- 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.

Possible shortages of, or our inability to obtain, the necessary raw materials that we currently use and intend to use in the future, including in our 3D printing manufacturing processes, could limit our ability to operate and grow our business.

We purchase some raw materials for our manufacturing processes from single suppliers, including polymer powders that currently are used in our 3D printing processes. Because we rely on these few suppliers and generally maintain a forward inventory of these materials sufficient only for approximately six months of supply, there are a number of risks in our business, including:

- potential shortages of these key raw materials;
- potential delays in qualifying a new source of these key raw materials if our current suppliers are unable to supply us with materials that meet our specifications, pass our internal quality control requirements, and meet regulatory requirements;
- discontinuation of a material or other component on which we rely;
- potential insolvency or change of control transactions involving our suppliers; and
- reduced control over delivery schedules, quality and costs.

We currently depend on sole source suppliers for the supply of polymer and metal powders. These sole source suppliers may be unwilling or unable to supply the powders to us reliably, continuously and at the levels we anticipate or are required by the market. We may incur added costs or delays in identifying and qualifying replacement suppliers. In addition, because these suppliers supply large portions of the markets for these materials, there is competition for such supply. As a result of such competition, the prices for these supplies may increase and their availability to us may decrease.

If any of our key suppliers were to decide to discontinue or limit the supply of a raw material that we use, the unanticipated change in the availability of supplies could cause delays in, or loss of, sales, increased production or related costs and damage to our reputation. In addition, because we use a limited number of suppliers, price

increases by our suppliers may have an adverse effect on our results of operations, as we may be unable to find an alternative supplier who can supply us at a lower price. As a result, the loss of a limited source supplier could adversely affect our relationships with our customers and our results of operations and financial condition.

We are dependent on third-party suppliers for important manufactured components included in our products, as well as for services that are essential to our manufacturing processes. The loss of any of these suppliers, or their inability to provide us with an adequate supply of components or to complete finishing or other manufacturing services, could limit our ability to operate and grow our business.

We rely on third-party suppliers to manufacture all of the implant components, packaging materials, and instrumentation used in our joint replacement products that we do not currently manufacture ourselves. Currently, our in-house manufacturing is limited to our iJigs and the majority of the tibial components used in our implants. We outsource the manufacture of the remainder of the tibial components and femoral and other implant components to third-party suppliers. While we plan to establish additional internal manufacturing capabilities for our implant components, we also expect that we will continue to rely on third-party suppliers to manufacture and supply certain of our implant components. For us to be successful, these manufacturers must be able to provide us with these components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and, in particular, on a timely basis. Our anticipated growth could strain the ability of our suppliers to manufacture and deliver an increasingly large supply of implants and components. Manufacturers often experience difficulties in scaling up production, including problems with quality control and assurance.

We generally purchase our outsourced implant components through purchase orders and do not have long-term contractual arrangements with any of our key suppliers. As a result, our suppliers have no obligation to manufacture for us or sell to us any given quantity of implant components. Without such contractual commitments, we could face difficulties in obtaining acceptance for our purchase orders, which could impair our ability to purchase adequate quantities of our implant components. If we are unable to obtain sufficient quantities of high-quality, individually-made components to meet demand on a timely basis, we could lose customers, our reputation may be harmed and our business would suffer. In addition, we currently depend on sole source suppliers for the supply of the reusable instrument trays and related logistics associated with our implant products. These sole source suppliers may be unwilling or unable to supply the trays and logistics services to us reliably, continuously and at the levels we anticipate or are required by the market.

We utilize a "just-in-time" manufacturing and delivery model, with minimal levels of inventories, which could leave us vulnerable to delays or shortages of key components or materials necessary for our products or delays in delivering our products. Any such shortages or delays could result in our inability to satisfy consumer demand for our products in a timely manner or at all, which could harm our reputation, future sales, profitability and financial condition.

As all of our products are individually-made to fit an individual patient, we can assemble our products only after we receive orders from customers and must utilize "just-in-time" manufacturing processes. Supply lead times for components used in our products may vary significantly and depend upon a variety of factors, such as:

- the location of the supplier and proximity to our facilities in Massachusetts;
- the availability of raw materials purchased by our suppliers;
- workforce availability and skill required by the suppliers;
- the complexity in manufacturing the component and general demand for the component;
- delays and disruptions in the manufacturing processes of our vendors; and
- disruptions in the supply chain due to weather conditions and natural disasters affecting suppliers, our employees, and freight carriers.

We generally maintain minimal inventory levels, except for inventories of raw materials used in our 3D printing and manufacturing processes. As a result, an unexpected shortage of supply of key components used to manufacture our products, or an unexpected and significant increase in the demand for our products, could lead to inadequate inventory and delays in shipping our products to customers. Any such delays could result in lost sales and harm to our relationships with surgeons, especially in the event of a missed surgery, which could in turn harm our profitability and financial condition.

Moreover, our suppliers are dependent on commercial freight carriers to deliver implant components to our facilities, and we are dependent on commercial freight carriers to deliver our finished products to hospitals and surgeons. If the operations of these carriers are disrupted for any reason, we may be unable to deliver our products to our customers on a timely basis. If we cannot deliver our products in an efficient and timely manner, our customers may reduce their orders from us and our revenues and operating profits could materially decline. In a rising fuel cost environment, our and our suppliers' freight costs will increase. If freight costs materially increase and we are unable to pass that increase along to our customers for any reason or otherwise offset such increases in our cost of revenues, our gross margin and financial results could be adversely affected.

Our information technology systems are critical to our business. System management and implementation issues and system security risks could disrupt our operations, which could have a material adverse impact on our business and operating results.

We rely on the efficient and uninterrupted operation of complex information technology systems. All information technology systems are vulnerable to damage or interruption from a variety of sources. As our business has grown in size and complexity, the growth has placed, and will continue to place, significant demands on our information technology systems.

The iFit software applications we have developed for our existing products are critical for efficiently and correctly designing customized implants and iJigs. These applications require maintenance and further improvements in design automation in order to continue increasing productivity of the design process. If we fail to meet our goals for design automation and productivity, this may impact our ability to reduce production costs. Furthermore, bugs or errors in these complex iFit software applications could cause production delays or product defects, which may lead to customer dissatisfaction or possibly even product recalls.

Our development of new products depends on our capability to adapt our iFit concepts and applications to new requirements. It may be more difficult than anticipated to make such adjustments, which could lead to delays or limitations in our ability to develop new, innovative products. Moreover, changes in privacy laws could increase the risk we are exposed to in managing patient data, and could limit some of the applications of that data in our business. In addition, experienced computer programmers and hackers may be able to penetrate our network security and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. The costs to eliminate or alleviate security problems or viruses could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, net revenues and operating results.

Risks related to our international operations

We are exposed to risks related to our international operations and failure to manage these risks may adversely affect our operating results and financial condition.

We sell our products internationally in Germany, the United Kingdom, Austria, Ireland, Switzerland, Singapore and Hong Kong. We expect that our international activities will increase over the foreseeable future as we continue to pursue opportunities in international markets. During each of the six months ended June 30, 2016 and 2015, approximately 24% and 27% of our revenue was attributable to our international customers, respectively, and as of June 30, 2016, approximately 5% of our employees were located outside the United States. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subjects us to extensive U.S., EU and other foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Therefore, we are subject to risks associated with having international operations. These international operations will require significant management attention and financial resources.

International operations are subject to inherent risks, and our future results could be adversely affected by a number of factors, including:

- requirements or preferences for domestic products or solutions, which could reduce demand for our products;
- differing existing or future regulatory and certification requirements;
- extraterritorial effects of U.S. laws such as the Foreign Corrupt Practices Act;

- effects of foreign anti-corruption laws, such as the U.K. Bribery Act 2010, or the Bribery Act;
- changes in foreign medical reimbursement policies and programs;
- management communication and integration problems related to entering new markets with different languages, cultures and political systems;
- complex data privacy requirements and labor relations laws;
- greater difficulty in collecting accounts receivable and longer collection periods;
- difficulties in enforcing contracts;
- difficulties and costs of staffing and managing foreign operations;
- labor force instability;
- the uncertainty of protection for intellectual property rights in some countries;
- potentially adverse regulatory requirements regarding our ability to repatriate profits to the United States;
- potentially adverse tax consequences, including on the repatriation profits to the United States;
- tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell our products in certain foreign markets; and
- political and economic instability and terrorism.

Our international operations expose us to risks of fluctuations in foreign currency exchange rates.

Our international operations expose us to risks of fluctuations in foreign currency exchange rates. To date, a significant portion of our international sales have been denominated in euros. We do not currently hedge any of our foreign currency exposure. As a result, a decline in the value of the euro against the U.S. dollar could have a material adverse effect on the gross margins and profitability of our international operations. In addition, sales to countries that do not utilize the euro could decline as the cost of our products to our customers in those countries increases or as the local currencies decrease. In addition, because our financial statements are denominated in U.S. dollars, a decline in the euro would negatively impact our overall revenue as reflected in our financial statements. To date, we have not used risk management techniques to hedge the risks associated with these fluctuations. Even if we were to implement hedging strategies, not every exposure can be hedged and, where hedges are put in place based on expected foreign currency exchange exposure, they are based on forecasts that may vary or that may later prove to have been inaccurate. As a result, fluctuations in foreign currency exchange rates or our failure to successfully hedge against these fluctuations could have a material adverse effect on our operating results and financial condition.

Risks related to managing our future growth

We expect to grow our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research and development, manufacturing, manufacturing engineering, regulatory affairs, sales, marketing and distribution and general administration, some of whom we will require to have specific technical skills that are in high demand. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities to devote time to managing these growth activities. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our inability to effectively manage the expansion of our operations may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional products. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced, and we may not be able to implement our business strategy. In addition, we may consider further expanding our operations through potential acquisitions. Potential and completed acquisitions and strategic investments involve numerous risks, including diversion of management's

attention from our core business, problems assimilating the purchased technologies or business operations and unanticipated costs and liabilities. Our future financial performance and our ability to commercialize products and compete effectively will depend, in part, on our ability to effectively manage any future growth, including growth through acquisitions.

Our future success depends on our ability to retain our Chief Executive Officer, Chief Technology Officer and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the medical device industry expertise of Philipp Lang, M.D., our Chief Executive Officer, and Daniel Steines, M.D., our Chief Technology Officer, as well as the other principal members of our management, scientific and development teams. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. In addition, we do not carry key-man insurance on any of our executive officers or employees and may not carry any key-man insurance in the future.

If we lose one or more of our executive officers, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous medical device companies for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited. Our Board of Directors is currently conducting a search for a new Chief Executive Officer. Our continued success will depend on our ability to successfully transition from Dr. Lang to a new Chief Executive Officer. The transition from Dr. Lang to a new Chief Executive Officer may cause disruption in our business, strategic and employee relationships, which may delay or prevent the achievement of our business objectives. The search for a permanent Chief Executive Officer may take many months or more, further exacerbating these factors. During the Chief Executive Officer transition period, there may be uncertainty among investors, employees, creditors and others concerning our future direction and performance. Any disruption or uncertainty could have a material adverse effect on our results of operations and financial condition and the market price of our common stock.

Our management could have interests that conflict with our interests and the interests of our shareholders.

We are party to revenue share agreements with certain past and present members of our scientific advisory board and our Chief Executive Officer that relate to these individuals' participation in the design and development of our products and related intellectual property. Compensation under these agreements for services rendered by these individuals includes a product revenue share. The existence of the revenue share arrangement may create a conflict of interest. For example, these advisors and our Chief Executive Officer may favor decisions that result in our making expenditures and allocating resources that increase revenue but do not result in profits or do not result in profits as great as other expenditures and allocations of resources would. Our Chief Executive Officer's equity interest, through his common stock and option ownership may, depending on the level of his equity interest and the level of our revenues, reduce this conflict. If any such decisions were made, however, our business could be harmed.

Risks related to our intellectual property and potential litigation

If we are unable to obtain, maintain or enforce sufficient intellectual property protection for our products and technologies, or if the scope of our intellectual property protection is not sufficiently broad, our competitive position could be harmed or we could be required to incur significant expenses to enforce our rights.

We rely primarily on patent, copyright, trademark and trade secret laws, know-how and continuing technological innovation, as well as confidentiality and non-disclosure agreements and other methods, to protect the intellectual property related to our technologies and products. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

We hold, or have in-licensed rights with respect to, patents and patent applications and have applied for additional patent protection relating to certain existing and proposed products and processes. While we generally

apply for patents in those countries where we intend to make, have made, use or sell patented products, we may not accurately predict all of the countries where patent protection will ultimately be desirable. If we fail to timely file a patent application in any such country or fail to properly pursue an application through to the issuance of a patent, we may be precluded from doing so at a later date. Furthermore, our patent applications may not issue as patents. The rights granted to us under our patents, including prospective rights sought in our pending patent applications, may not be meaningful or provide us with any commercial advantage and they could be opposed, contested or circumvented by our competitors or could be declared invalid or unenforceable in judicial or in a wide variety of administrative proceedings including opposition, interference, re-examination, post-grant review, inter parties review, nullification and derivation proceedings. In such proceedings, third parties can raise objections against the initial grant of the patent. In the course of some such proceedings, which may continue for a protracted period of time, we may be compelled to limit the scope of the challenged claims, or may lose them altogether. In addition, our pending patent applications include claims to material aspects of our products and procedures that are not currently protected by issued patents. The process of applying for patent protection itself is time consuming and expensive. The failure of our patents to protect our products and technologies adequately might make it easier for our competitors to offer the same or similar products or technologies. Competitors may be able to design around our patents or develop products that provide outcomes that are comparable to ours without infringing on our intellectual property rights.

We may be involved in lawsuits to protect or enforce our intellectual property rights, which could be expensive, time consuming and unsuccessful.

If a competitor infringes or otherwise violates one of our patents, the patents of our licensors, or our other intellectual property rights, enforcing those patents, trademarks and other rights may be difficult, time consuming or unsuccessful. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, in whole or part, or may refuse to stop the other party in such infringement proceeding from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management's attention from managing our business. Moreover, we may not have sufficient resources or desire to defend our patents or trademarks against challenges or to enforce our intellectual property rights.

In particular, on February 29, 2016, we filed a lawsuit against Smith & Nephew, Inc. (“Smith & Nephew”) in the United States District Court for the District of Massachusetts Eastern Division. The lawsuit alleges that Smith & Nephew’s Visionaire® patient-specific instrumentation, as well as the implants systems used in conjunction with the Visionaire instrumentation, infringe eight of our patents, and requests monetary damages for willful infringement 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 a meritorious case, we cannot predict the outcome of this lawsuit.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, and our business would be harmed.

In addition to the protection afforded by patents, we rely on confidential proprietary information, including trade secrets, and know-how to develop and maintain our competitive position, especially with respect to our proprietary software used in the iFit Design and iFit Printing aspects of our technology platform. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information, however, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentiality of our

confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a

competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.

We have entered into license agreements with third parties providing us with rights under various third-party patents and patent applications, including the rights to prosecute patent applications and to enforce patents. Certain of these license agreements impose and, for a variety of purposes, we may enter into additional licensing and funding arrangements with third parties that also may impose, diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. Under certain of our existing licensing agreements, we are obligated to pay royalties on net product sales of our products, pay a percentage of sublicensing revenues, make other specified payments relating to our products or pay license maintenance and other fees. We also have diligence and development obligations under certain of these agreements that we are required to satisfy. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our company. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

In the future, we may not be able to license additional intellectual property rights that we need for our business. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could harm our business significantly.

In the future, we may need to obtain additional licenses from others to expand our product lines, advance our technology or allow commercialization of our current or future products. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our products or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, products or future methods or products, resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

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, Orthopedic Innovations, Inc., alleging that our iUni G2 and iDuo G2 partial knee replacement surgical techniques infringe an existing patent. Among other relief, the plaintiff sought damages for willful infringement, attorney’s fees, costs and a permanent injunction. On March 28, 2016, the plaintiff voluntarily dismissed the action. Because the action was dismissed without prejudice, the plaintiff could sue us again on the same patent.

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;
- 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.

We may not be able to adequately protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign

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countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we will not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to enable us to terminate infringing activities.

We do not have patent rights in certain foreign countries in which a market may exist. We have filed patent applications only in the United States and fewer than 18 other countries, many of which are in the European Union, and we therefore lack any patent protection in all other countries. In countries where we do not have significant patent protection, we are unlikely to stop a competitor from marketing products in such countries that are the same as or similar to our products. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products, and our competitive position in the international market would be harmed.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the United States patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The United States Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

If product liability lawsuits are brought against us, our business may be harmed, and we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for knee and hip replacement procedures. Knee replacement surgery involves significant risk of serious complications, including bleeding, infection, instability, dislocation, nerve injury and death. Hip replacement surgery involves significant risk of serious complications including bleeding, infection, dislocation, leg length discrepancy, nerve injury and death. In addition, joint replacement surgery involves product risks, including failures over time due to polyethylene wear and aseptic loosening, which is a condition caused by wear debris generated by the implant. We or our suppliers could suffer breaches to our sterilization procedures, which could cause contamination of the affected components and products we market and ultimately could cause infections in patients.

Moreover, patients may be dissatisfied with the results of joint replacement surgery even if there is no medical complication. Furthermore, if orthopedic surgeons are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient

injury. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients.

We have had product liability claims relating to our products asserted against us in the past, and some product liability claims currently are outstanding. No claim to date either individually, or in the aggregate, has resulted, in a material negative impact on our business. In light of the nature of our business, it is likely we will continue to be subject to product liability claims in the future, some of which could have a negative impact on our business.

Regardless of the merit or eventual outcome, product liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients, especially in the event of a class action lawsuit;
- product recalls;
- loss of revenue;
- the inability to commercialize new products or product candidates; and
- diversion of management attention from pursuing our business strategy and may be costly to defend.

Our existing product liability insurance coverage may be inadequate to protect us from any liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers.

In addition, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources and adversely affect or eliminate the prospects for commercialization or sales of a product or product candidate that is the subject of any such claim.

Risks related to government regulation

Our medical device products are subject to extensive governmental regulation both in the United States and abroad, and our failure to comply with applicable requirements could cause our business to suffer.

Our products are classified as medical devices and are subject to extensive regulation by the FDA and other federal, state and foreign governmental authorities. These regulations relate to manufacturing, labeling, sale, promotion, distribution, importing and exporting and shipping of our products. If we fail to comply with applicable laws and regulations it could jeopardize our ability to sell our products and result in enforcement actions such as:

- untitled letters, warning letters, fines, injunctions or civil penalties;
- termination of distribution authorizations;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal of the FDA or other regulators to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products;
- withdrawal of the CE Certificates of Conformity, which authorize us to apply the CE Mark to our products and are necessary to sell our products within the European Economic Area, or EEA, or delay in obtaining these certificates; or

- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

The regulations to which we are subject are complex and have tended to become more stringent over time, making obtaining clearances and maintaining compliance increasingly difficult. If we fail to obtain and maintain necessary FDA clearances and approvals for our products and indications or if clearances and approvals for future products and indications are delayed or not issued, our business would be harmed.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance from the FDA through the filing of a 510(k) premarket notification or approval from the FDA pursuant to a premarket approval application, or PMA, unless the device is specifically exempt from premarket review. The clearance or approval that is required will depend upon how the product is classified by the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose low to moderate risk are placed in either Class I or II, which, absent an exemption, requires the manufacturer to submit to the FDA a premarket notification requesting permission for commercial distribution, which is known as 510(k) clearance. Class III devices, such as life-sustaining or life-supporting devices or devices that are of substantial importance in preventing impairment of human health or which present a potential unreasonable risk of illness or injury, require approval of a PMA to provide reasonable assurance of safety and effectiveness.

In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including technical, pre-clinical, clinical trial, manufacturing and labeling data.

In order to obtain a PMA and, in some cases, a 510(k) clearance, a product sponsor must conduct well controlled clinical trials designed to test the safety and effectiveness of the product. To date, we have not been required to conduct clinical studies or to obtain clinical data in order to obtain 510(k) clearance in the United States for our products. Additionally, to date, we have not been required to complete clinical studies in connection with obtaining regulatory approval for the sale of our products outside the United States. Conducting clinical trials generally entails a long, expensive and uncertain process that is subject to delays and failure at any stage. The data obtained from clinical trials may be inadequate to support approval or clearance of a submission. In addition, the occurrence of unexpected findings in connection with clinical trials may prevent or delay obtaining approval or clearance. If we conduct clinical trials, they may be delayed or halted or may be inadequate to support approval or clearance, for numerous reasons, including:

- the FDA or other regulatory authorities may place a clinical trial on hold or partial hold;
- institutional review boards and third-party clinical investigators may delay or reject our trial protocol;
- third-party clinical investigators may decline to participate in a trial or may not perform a trial on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other FDA requirements;
- the FDA, other regulatory authorities or an institutional review board may place a clinical trial on hold;
- patients may not enroll in clinical trials, or patient follow-up may not occur, at the rate we expect;
- patients may not comply with trial protocols;
- third party clinical investigators may decline to participate in a trial or may not perform a trial on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or other FDA requirements;
- third-party organizations may not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical trials or manufacturing facilities may, among other things, require us to undertake corrective action or suspend, terminate or invalidate our clinical trials;
- changes in governmental regulations or administrative actions; and
- the interim or final results of the clinical trials may be inconclusive or unfavorable as to safety or effectiveness.

The FDA's 510(k) clearance process for each device or modification usually takes from three to 12 months, but may last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained.

In the United States, all of our FDA-cleared products have been cleared without the use of a PMA under the 510(k) clearance process. Additionally, we have in the past, and may in the future, determine that certain changes or modifications to our products or other cleared devices may not significantly affect the safety or effectiveness of the device, and, therefore, may not require a 510(k) submission. In such situations, the changes are assessed using the FDA guidance for determining when to submit a 510(k) for a change to an existing device. However, the FDA may not agree with our determination and may, instead, require that we seek 510(k) clearance of such products or other cleared devices or, potentially, require us to submit a PMA.

If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. The FDA may demand that we obtain a PMA prior to marketing certain of our future products. In addition, if the FDA disagrees with our determination that a product we currently market is eligible for clearance under the premarket notification process of Section 510(k) of the FDCA, the FDA may require us to submit a PMA in order to continue marketing the product. Further, even with respect to those future products where a PMA is not required, we may not be able to obtain the 510(k) clearances with respect to those products.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of products we are developing or impact our ability to modify any of our products for which we receive regulatory clearance or approval in the future on a timely basis. Any change in the laws or regulations that govern the clearance and approval processes relating to the products we are developing could make it more difficult and costly to obtain clearance or approval for such products, or to produce, market and distribute products for which we receive regulatory approval or clearance in the future.

To date, we have used the CE Marking process to satisfy the conformity standards required to market and sell our joint replacement products in the EU. In the CE Marking process, a medical device manufacturer must carry out a clinical evaluation of its medical device to demonstrate conformity with the relevant Essential Requirements. This clinical evaluation is part of the product's technical file. A clinical evaluation includes an assessment of whether a medical device's performance is in accordance with its intended use, that the known and foreseeable risks linked to the use of the device under normal conditions are minimized and acceptable when weighed against the benefits of its intended purpose. The clinical evaluation conducted by the manufacturer must also address any clinical claims, the adequacy of the device labeling and information (particularly claims, contraindications, precautions and warnings) and the suitability of related instructions for use. This assessment must be based on clinical data, which can be obtained from clinical studies conducted on the device being assessed, scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or both clinical studies and scientific literature. With respect to implantable devices or devices classified as Class III in the EU, the manufacturer must conduct clinical studies to obtain the required clinical data, unless reliance on existing clinical data from similar devices can be justified.

As part of the conformity assessment process, depending on the type of device, an entity authorized to conduct the conformity assessment, which is referred to as a Notified Body, will review the manufacturer's clinical evaluation process, assess the clinical evaluation data of a representative sample of the device's subcategory or generic group, or assess all the clinical evaluation data, verify the manufacturer's assessment of that data and assess the validity of the clinical evaluation report and the conclusions drawn by the manufacturer. We conduct clinical studies to obtain clinical data as part of the clinical evaluation process. The conduct of clinical studies to obtain clinical data as part of the described clinical evaluation process can be expensive and time-consuming.

Any delay in, or failure to receive or maintain, clearance or approval for our products under development could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation and the

perceived safety and efficacy of our products.

Even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-marketing studies. For example, as a condition of approval, we could be

required to conduct a post-approval study, as well as an enhanced surveillance study. Failure to conduct required studies in a timely manner could result in the revocation of the 510(k) clearance or PMA approval for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

Even after we receive a CE Design Examination Certificate ("CE Certificate") enabling us to affix the CE Mark to a product and to sell our product in the EEA and Switzerland, a Notified Body or a competent authority may require post-marketing studies of our product. Failure to comply with such requirements in a timely manner could result in the withdrawal of our CE Certificate and the recall or withdrawal of our product from the market in the European Union, which would prevent us from generating revenue from sales of that product in the EEA and Switzerland. Moreover, each CE Certificate is valid for a maximum of five years. Our CE Certificates are valid through May 8, 2021 for our iTotal CR product, December 2, 2017 for our iUni product, June 11, 2019 for our iDuo product and March 5, 2020 for our iTotal PS product. At the end of each period of validity we are required to apply to the Notified Body for a renewal of the CE Certificate. There may be delays in the renewal of the CE Certificate or the Notified Body may require modifications to our products or to the related technical files before it agrees to issue the new CE Certificate.

Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

The FDA or the EU may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or may impact our ability to modify our currently approved or cleared products on a timely basis. For example, as part of the Food and Drug Administration Safety and Innovation Act of 2012, or the FDASIA, the U.S. Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Similarly, the EU may reclassify any of our Class IIa products as Class IIb or Class III in the EU. In either such event, the process for attaining regulatory approval of our products would be more difficult and costly and would take additional time compared to the regulatory clearance processes that have been applicable to our products to date.

The FDA could also reclassify some or all of our products that are currently classified as Class II to Class III requiring additional controls, clinical studies and submission of a PMA for us to continue marketing and selling those products. Under new changes instituted by the FDASIA, the FDA may now change the classification of a medical device by administrative order instead of by regulation. Although the revised process is simpler, the FDA must still publish a proposed order in the Federal Register, hold a device classification panel meeting and consider comments from affected stakeholders before issuing the reclassification order. The FDA may reclassify any of our Class II devices into Class III and require us to submit a PMA for FDA review and approval of the safety and effectiveness of our products.

Modifications to our currently FDA-cleared products or the introduction of new products may require new regulatory clearances or approvals or require us to recall or cease marketing our current products until clearances or approvals are obtained.

Modifications to our products may require new regulatory approvals or clearances or require us to recall or cease marketing the modified products until these clearances or approvals are obtained. Any modification to one of our 510(k)-cleared products that would constitute a major change in its intended use or any change that could significantly affect the safety or effectiveness of the device would require us to obtain a new 510(k) marketing clearance and may even, in some circumstances, require the submission of a PMA if the change raises complex or novel scientific issues or the product has a new intended use. We may be required to submit extensive pre-clinical and clinical data depending on the nature of the changes. We may not be able to obtain additional 510(k) clearances or premarket approvals for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and operating results.

The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. We have modified some of our 510(k) cleared

products, and have determined based on our review of the applicable FDA guidance that in certain instances the changes did not require new 510(k) clearances or PMA approval. If the FDA disagrees with

our determination and requires us to seek new 510(k) clearances or PMA approval for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or distribution of our products or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Furthermore, potential changes to the 510(k) program may make it more difficult for us to make modifications to our previously cleared products, by either imposing more strict requirements on when a new 510(k) clearance for a modification to a previously cleared product must be submitted or applying more burdensome review criteria to such submissions. In July and December 2011, the FDA issued draft guidance documents addressing when to submit a new 510(k) clearance due to modifications to 510(k)-cleared products and the criteria for evaluating substantial equivalence. The July 2011 draft guidance document was ultimately withdrawn as the result of the passage of the FDASIA. As a result, the FDA's original guidance document regarding 510(k) modifications, which dates back to 1997, remains in place. It is uncertain when the FDA will seek to issue new guidance on product modifications. Any efforts to do so could result in a more rigorous review process and make it more difficult to obtain clearance for device modifications.

The FDA may not grant 510(k) clearance or PMA approval of our future products, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

Any future products that we develop, including our iTotal Hip replacement products, will require FDA clearance of a 510(k) or FDA approval of a PMA. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products.

In December 2012 the FDA issued guidance documents intended to explain the procedures and criteria the FDA will use in assessing whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for substantive review. Under the "Refuse to Accept" guidance, the FDA conducts an early review against specific acceptance criteria to inform 510(k) and PMA submitters if the submission is administratively complete, or if not, to identify the missing element(s). Submitters are given the opportunity to provide the FDA with the identified information. If the information is not provided within a defined time, the submission will not be accepted for FDA review. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

In 2015 we submitted an application for 510(k) clearance of iTotal Hip with the FDA. In the course of its review of that application, the FDA raised a number of questions, and we were not able to address all of those questions within the allowed review timeline. Therefore, after consultation with the FDA, we elected to withdraw the application. We plan to address the questions raised by the FDA, including conducting any associated testing, and submit a new application for 510(k) clearance of iTotal Hip in the second half of 2016 However, if we are not able to address the questions raised by the FDA in our revised application for 510(k) clearance, or if the FDA raises additional questions, we may be further delayed in receiving clearance or the iTotal Hip or may ultimately be unable to receive clearance, which would have an adverse effect on our ability to expand our business.

Our cleared and approved products are, and any future products will be, subject to post-marketing restrictions, and we may be subject to substantial penalties if we fail to comply with all applicable regulatory requirements.

The products for which we have obtained regulatory clearance or approval are, and any of our future products will be, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such products, subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, Quality System regulations relating to manufacturing, quality control and quality assurance and corresponding maintenance of records and documents. In addition, we must report corrections and removals to the FDA where the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act caused by the device that may present a risk to health, and maintain records of other corrections or removals. If we receive regulatory clearance or approval of additional products in the future, the clearance or approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of clearance or approval, and the accompanying label may limit the approved use of our product, which could limit sales of the product.

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The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, or DOJ, and state Attorneys General, closely regulate the manufacturing, marketing and promotion of medical devices. Violations of the FDCA and other statutes, including the False Claims Act, may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown safety issues or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in:

- litigation involving patients who underwent procedures using our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- repair, replacement, refunds, recalls or detention of our products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of regulatory clearance or approval;
- damage to relationships with any potential collaborators;
- operating restrictions or partial suspension or total shutdown of production;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure;
- consent decrees; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements can also result in significant financial penalties.

We may fail to obtain or maintain foreign regulatory approvals to market our products in other countries, which could harm our business.

To market and sell our products in countries outside the United States, we must seek and obtain regulatory approvals, certifications or registrations and comply with the laws and regulations of those countries. These laws and regulations, including the requirements for approvals, certifications or registrations and the time required for regulatory review, vary from country to country. Obtaining and maintaining foreign regulatory approvals, certifications or registrations are expensive and we cannot be certain that we will maintain or receive regulatory approvals, certifications or registrations in any foreign country in which we currently market or plan to market our products.

The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, the product must be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain or maintain regulatory approvals, certifications or registrations in any foreign country in which we currently market or plan to market our products, our ability to generate revenue will be harmed.

We may also incur significant costs in attempting to obtain and in maintaining foreign regulatory clearances, approvals or qualifications. Foreign regulatory agencies, as well as the FDA, periodically inspect manufacturing facilities both in the United States and abroad. If we experience delays in receiving necessary qualifications, clearances or approvals to market our products outside the United States, or if we fail to receive those qualifications, clearances or approvals, or if we fail to comply with other foreign regulatory requirements, we and our distributors may be unable to market our products or enhancements in international markets effectively, or at all. Additionally, the imposition of new requirements may significantly affect our business and our products. We may not be able to adjust to such new requirements, which may adversely affect our business.

If we or our suppliers fail to comply with ongoing FDA, EU or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to additional restrictions or withdrawal from the market, which would harm our business.

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our third-party suppliers are required to comply with the FDA's Quality System Regulation, or QSR, and the applicable regulatory requirements in the EU on product assessments and quality system assessments. In the EU, compliance with harmonized standards prepared under a mandate from the European Commission and referenced in the Official Journal of the EU, or harmonized standards, serve as a presumption of conformity with the relevant Essential Requirements under the Medical Devices Directive 93/42/EEC, as amended. These FDA regulations and EU standards cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products and expected future products.

Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. Compliance with harmonized standards in the EU is also subject to regular review through the conduct of inspection by Notified Bodies or other regulatory bodies. In September 2013, the European Commission issued a new recommendation on audits and assessments performed by Notified Bodies in the field of medical devices. According to this recommendation, Notified Bodies have to perform unannounced audits to verify continuous compliance with applicable legal obligations under Directive 93/42/EEC. We must permit and allow unimpeded access for Notified Body staff to conduct unannounced audits in order to maintain our CE Certificate. If we, or our manufacturers, fail to adhere to QSR requirements in the United States or regulatory requirements in the EU, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances or CE Certificate, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

The FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA inspected our Bedford, Massachusetts facility and quality system in June 2015 and our Wilmington facility in September 2015. While none of these inspections have resulted in any significant observations or warning letters, we cannot provide assurance that we can maintain a comparable level of regulatory compliance in the future at our facilities or that future inspections will have the same result.

The British Standards Institute, or BSI, an independent global notified body, conducts annual assessments of our quality management system in order to confirm that our quality management system complies with the requirements of ISO13485 in all material respects and periodic full recertification audits of our quality management system in order to confirm that we comply with the requirements of the Medical Devices Directive 93/42/EEC. Our last full recertification audit was completed in December 2015. The BSI completed an unannounced inspection in May 2016 of all applicable EU requirements. We expect that BSI will continue to conduct annual audits, or unannounced audits, to assess our compliance with the applicable EU requirements.

The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or applicable regulatory requirements in the EU, or the failure to timely and adequately respond to any adverse inspectional observations, nonconformances or product safety issues, could result in any of the enforcement actions or sanctions described above under the risk factor captioned "-Our medical device products are subject to extensive governmental regulation both in the United States and abroad, and our failure to comply with applicable requirements could cause our business to suffer." Any of these sanctions could have a material adverse effect on our reputation,

business, results of operations and financial condition. Furthermore, our key third-party manufacturers may not currently be or may not continue to be in compliance with all applicable regulatory

requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions, which could harm our business.

Under the FDA medical device reporting, or MDR, regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. The decision to file an MDR involves a judgment by us as the manufacturer. We have made decisions that certain types of events are not reportable on an MDR; however, there can be no assurance that the FDA will agree with our decisions. If we fail to report MDRs to the FDA within the required timeframes, or at all, or if the FDA disagrees with any of our determinations regarding the reportability of certain events, the FDA could take enforcement actions against us, which could have an adverse impact on our reputation and financial results.

Additionally, all manufacturers placing medical devices in the market in the EU are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the competent authority in whose jurisdiction the incident occurred. In the EU, we must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant National Competent Authorities of the EU countries. Manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its European Authorized Representative to its customers and to the end users of the device through Field Safety Notices.

Any such adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events involving our products have been reported to us in the past, and similar adverse events may occur in the future. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

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. The recalled products were manufactured and distributed from our Wilmington manufacturing facility between July 18, 2015 and August 28, 2015. We isolated the root cause to a step in our ethylene oxide sterilization process conducted by a vendor. We have since completed final testing and implemented corrective actions, and we 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, including by potentially damaging our reputations with consumers, healthcare providers, distributors and other business partners. We have also experienced other limited recalls in the past related to manufacturing defects, labeling updates and packaging inconsistencies.

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 a market withdrawal or a stock recovery 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 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 orthopedic surgeons, 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 be subject to enforcement action if we engage in improper marketing or promotion of our products for which we have received regulatory clearance or approval. Any such enforcement action could result in significant fines, costs and penalties and could result in damage to our reputation.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. Use of a device outside its cleared or approved indications is known as "off-label" use. We believe that the specific surgical procedures for which our products are marketed fall within the scope of the surgical applications that have been cleared by the FDA. However, physicians may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. If the FDA determines that our promotional materials or other product labeling constitute promotion of an unapproved, or off-label use, it could request that we modify our materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties.

Other federal, state and foreign regulatory agencies, including the U.S. Federal Trade Commission, have issued guidelines and regulations that govern how we promote our products, including how we use endorsements and testimonials. If our promotional materials are inconsistent with these guidelines or regulations, we could be subject to enforcement actions, which could result in significant fines, costs and penalties. Our reputation could also be damaged and the adoption of our products could be impaired. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

In the EU, our medical devices may be promoted only for the intended purpose for which the devices have been CE Marked. Failure to comply with this requirement could lead to the imposition of penalties by the competent authorities of the EU Member States. The penalties could include warnings, orders to discontinue the promotion of the medical device, seizure of the promotional materials and fines. Our promotional materials must also comply with various laws and codes of conduct developed by medical device industry bodies in the EU governing promotional claims, comparative advertising, advertising of medical devices reimbursed by the national health insurance systems and advertising to the general public. If our promotional materials do not comply with these laws and industry codes we could be subject to penalties that could include significant fines. Our reputation could also be damaged and the adoption of our products could be impaired.

Legislative or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our products and to produce, market and distribute our products after clearance or approval is obtained.

Recent political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health programs, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. Such legislation and regulations may result in decreased reimbursement for medical devices or the procedures in which they are used, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products, generate sales and become or remain profitable.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of, or failure to receive, regulatory clearances or approvals for our new products would have a material adverse effect on our business, results of operations and financial condition.

Federal and state governments in the United States have recently enacted legislation to overhaul the nation's healthcare system. While the goal of healthcare reform is to expand coverage to more individuals, it also involves increased governmental price controls, additional regulatory mandates and other measures designed to constrain medical costs. The Patient Protection and Affordable Care Act significantly impacts the medical device industry. Among other things, the PPACA:

- imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, although this tax has been suspended for 2016 and 2017;
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to the U.S. Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per year through 2024, unless additional congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA which, among other things, reduced Medicare payments to several providers, including hospitals and imaging centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Risks related to other legal and compliance matters

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 purported securities class action lawsuit was filed against us, our chief executive officer and chief financial officer in the United States District Court for the District of Massachusetts, alleging, among other things, that the defendants violated federal securities laws by allegedly making misrepresentations or failing to 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 certification of the class, unspecified compensatory damages, interest, attorneys’

fees, expert fees and other costs. On August 3, 2016, the court granted our motion to dismiss in it its entirety, denied the plaintiffs' request to replead their allegations and dismissed the lawsuit. The plaintiffs may appeal the court's decision, and there can be no assurance that we would be successful either in an appeal

proceeding, or, if such a proceeding ends adversely to us, in any subsequent court proceeding. The class action lawsuit is described in more detail in Part II, Item 1, Legal Proceedings, of this Quarterly Report on Form 10-Q.

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. The substantial costs and diversion of management's attention in any such litigation could harm our business and a decision adverse to our interests in any such 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.

Our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.

The PPACA imposes, among other things, an excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States as of 2013, although this tax has been suspended for 2016 and 2017. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to $20 billion over the next decade. The Internal Revenue Service issued final regulations implementing the tax in December of 2012 that require, among other things, bi-monthly payments if the tax liability exceeds $2,500 for the quarter and quarterly reporting. The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law on December 18, 2015, includes a two year moratorium on the medical device excise tax imposed by Internal Revenue Code section 4191. Thus, the medical device excise tax does not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016 and ending on December 31, 2017. It is unclear at this time if the moratorium will be extended, and we are currently subject to the tax after December 31, 2017. Additionally, Congress could terminate the moratorium or further change the law related to the medical device tax, in a manner that could adversely affect us. During the six months ended June 30, 2016 and June 30, 2015, we incurred $0 and $0.4 million, respectively, in tax expense associated with the medical device tax in the United States, which is included in general and administrative expense.

Our relationships with healthcare providers, physicians and third party payors will be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, in the event of a violation, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third party payors will play a primary role in the recommendation and prescription and use of our products and any other product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians and third party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals, with data collection beginning in August 2013; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers.

Some state laws require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our financial results. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are

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considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services, or HHS, promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we or any of our service providers are found to be in violation of the promulgated patient privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and operating results. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health-care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks related to our common stock

An active trading market for our common stock may not be maintained.

Our common stock began trading on the NASDAQ Global Select Market on July 1, 2015. Prior to July 1, 2015, there was not a public market for our common stock. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares may not be maintained. If an active market for our common stock is not maintained, it may be difficult for you to sell your shares without depressing the market price for the shares or at all. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The price of our common stock is likely to be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price is likely to be volatile. The stock market in general and the market for medical device companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your original purchase price. The market price for our common stock may be influenced by many factors, including:

- a slowdown in the medical device industry or the general economy;
- actual or anticipated quarterly or annual variations in our results of operations or those of our competitors;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- actual or anticipated changes in our growth rate relative to our competitors;
- changes in earnings estimates or recommendations by securities analysts;
- fluctuations in the values of companies perceived by investors to be comparable to us;
- announcements by us or our competitors of new products or services, significant contracts, commercial relationships, capital commitments or acquisitions;
- competition from existing technologies and products or new technologies and products that may emerge;
- the entry into or modification or termination of agreements with our distributors;
- developments with respect to intellectual property rights;
- sales, or the anticipation of sales, of our common stock by us, our insiders or our other stockholders, including upon the expiration of contractual lock-up agreements;
- our ability to develop, obtain regulatory approval for and market new and enhanced products on a timely basis;
- changes in coverage and reimbursement policies by insurance companies and other third-party payors;
- our commencement of, or involvement in, litigation;
- additions or departures of key management or technical personnel; and
- changes in laws or governmental regulations applicable to us.

Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock; the actual or potential sales of some or all of those shares could reduce the market price of our common stock.

Our quarterly operating results are subject to substantial fluctuations, and you should not rely on them as an indication of our future results.

Our quarterly operating results have historically varied and may in the future vary significantly due to a combination of factors, many of which are beyond our control. These factors include:

- seasonality in demand for our products, with reduced orders during the summer months and around year-end, followed by reduced sales of our products during the first and third quarters as a result;
- our ability to meet the demand for our products;
- increased competition;
- the number, timing and significance of new products and product introductions and enhancements by us and our competitors;
- our ability to develop, introduce and market new and enhanced versions of our products on a timely basis;
- changes in pricing policies by us and our competitors;
- changes in the treatment practices of orthopedic surgeons;
- changes in distributor relationships and sales force size and composition;
- the timing of material expense- or income-generating events and the related recognition of their associated financial impact;
- fluctuations in foreign currency rates;
- ability to obtain reimbursement for our products;
- availability of raw materials;
- work stoppages or strikes in the healthcare industry;

- changes in FDA and foreign governmental regulatory policies, requirements and enforcement practices;
- import and export inspections, which could impact the timing of delivery for either supplies or finished goods;
- changes in accounting policies, estimates and treatments; and
- general economic factors.

We believe our quarterly sales and operating results may vary significantly in the future and period-to-period comparisons of our results of operations are not necessarily meaningful and should not be relied upon as indications of future performance. We may not be able to increase our sales, sustain our sales in future periods or achieve or maintain profitability in any future period. Any shortfalls in sales or earnings from levels expected by securities or orthopedic industry analysts could have an immediate and significant adverse effect on the trading price of our common stock in any given period.

Sale of a substantial number of our shares of common stock in the public market could cause the market price of our common stock to decline significantly, even if our business is doing well.

Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock, and sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

Moreover, certain holders of our common stock and holders of warrants to purchase our common stock have rights to require us to register their shares under the Securities Act, and to participate in future registrations of securities by us, subject to certain conditions.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our stock incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, and, in any event, we have filed a registration statement permitting shares of common stock issued on exercise of options to be freely sold in the public market. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain of our employees, executive officers and directors have entered or may enter into Rule 10b5-1 plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the employee, director or officer when entering into the plan, without further direction from the employee, officer or director. A Rule 10b5-1 plan may be amended or terminated in some circumstances. Our employees, executive officers and directors also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors and principal stockholders and their affiliates beneficially own in the aggregate, a substantial portion of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of ownership control may:

- delay, defer or prevent a change in control transaction that you may otherwise perceive to be beneficial;
- entrench our management or the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2015, we had federal net operating loss, or NOL, carryforwards of $278 million and state NOL carryforwards of $138 million available to reduce future taxable income. These federal and state NOL

carryforwards will begin to expire in 2020, if not utilized. Utilization of these NOL and tax credit carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and comparable provisions of state, local and foreign tax laws due to changes in ownership of our company that have occurred previously or that could occur in the future. We have completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation. The results of this study indicate that we experienced ownership changes, as defined by Section 382 of the Code. We have not identified NOLs that, as a result of these limitations, will expire unused. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we generate taxable income, our ability to use our pre-change NOL and tax credits carryforwards to reduce U.S. federal and state taxable income may be subject to further limitations, which could result in increased future tax liability to us. All or a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock, without stockholder approval, that could be used to institute a shareholder rights plan, or so called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders.

Our restated certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against our company and our directors and officers.

Our restated certificate of incorporation provides that, unless our board of directors otherwise determines, the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors or

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officers to our company or our stockholders, any action asserting a claim against us or any of our directors or officers arising pursuant to any provision of the General Corporation Law of the State of Delaware, or any action asserting a claim against us or any of our directors or officers governed by the internal affairs doctrine. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors or officers, which may discourage such lawsuits against us and our directors and officers.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, stockholders must rely on capital appreciation, if any, for any return on their investment.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the operation, development and growth of our business. Furthermore, any future debt agreements may also preclude us from paying or place restrictions on our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain with respect to your investment for the foreseeable future.

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

We are an "emerging growth company," or EGC, as defined in the JOBS Act, and may remain an EGC until the earlier of: (1) the last day of the year in which we have total annual gross revenues of $1 billion or more; (2) December 31, 2020; (3) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the first day of the year following the first year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30. For so long as we remain an EGC, we have and plan to continue to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or SOX Section 404, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not EGCs.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

Our common stock began trading on the NASDAQ Global Select Market on July 1, 2015. As a public company, and particularly after we are no longer an EGC, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NASDAQ Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract

and retain qualified members of our board of directors. We are currently evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack

of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to SOX Section 404 we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC after we become a public company, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

ITEM 2. UNREGISTERED SALES OF 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 overallotment 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.

As of June 30, 2016, we have used approximately $91.1 million of the net proceeds from the offering as follows: $5.9 million to purchase and install capital equipment to expand our manufacturing capacity, approximately $44.6 million to expand and support our sales and marketing efforts, and approximately $17.0 million to fund research, development and clinical activities and approximately $23.9 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.

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.

Date: August 11, 2016

CONFORMIS, INC.
By: /s/ Paul Weiner
Paul Weiner
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1†	Form of Retention Agreements of Certain Officers
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

† Indicates management contract or other compensatory plan, contract or arrangement.
* Furnished herewith.