ConforMIS Inc
Form 424B4
July 01, 2015

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Filed Pursuant to Rule 424(b)(4)
Registration No. 333-204384

9,000,000 shares

Common stock

This is an initial public offering of common stock by ConforMIS, Inc. We are selling 9,000,000 shares of common stock. The initial public offering price is $15.00 per share.

Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for listing on the NASDAQ Global Select Market under the symbol "CFMS".

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012, and as such, will be subject to certain reduced public reporting requirements.

	Per share	Total
Initial public offering price	$ 15.00	$ 135,000,000
Underwriting discounts and commissions(1)	$ 1.05	$ 9,450,000
Proceeds to ConforMIS, before expenses	$ 13.95	$ 125,550,000

(1) We have agreed to reimburse the underwriters for certain FINRA-related expenses. See "Underwriting" beginning on page 176 of this prospectus.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 1,350,000 shares of our common stock.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 12 of this prospectus.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to investors on or about July 7, 2015.

Joint Bookrunners

J.P. Morgan **Deutsche Bank Securities**

Co-Managers

Wells Fargo Securities **Canaccord Genuity** **Oppenheimer & Co.**

The date of this prospectus is June 30, 2015.

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Neither we nor the underwriters have authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. Neither we nor the underwriters take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

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PROSPECTUS SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the "Risk Factors," "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections and our consolidated financial statements and the related notes appearing elsewhere in this prospectus before making an investment decision. Unless the context otherwise requires, we use the terms "ConforMIS," "our company," "we," "us" and "our" in this prospectus to refer to ConforMIS, Inc., together with its wholly owned subsidiaries.

Our business

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 more than 30,000 knee implants in the United States and Europe. In recent clinical studies, iTotal CR, our cruciate-retaining total knee replacement implant and best-selling product, demonstrated superior clinical outcomes, including better function and greater patient satisfaction compared to traditional, off-the-shelf implants. We recently initiated the limited launch of iTotal PS, our posterior-stabilized total knee replacement implant which addresses the largest segment of the knee replacement market. We expect to submit an application for clearance of iTotal Hip, our first customized hip replacement implant, to the U.S. Food and Drug Administration, or FDA, in 2015.

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 patient-specific instrumentation, which we refer to as iJigs.

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

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

We believe our iFit technology platform enables a highly 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.

We own or exclusively in-license approximately 470 issued patents and pending patent applications that cover customized implants and patient-specific instrumentation, or PSI, for all major joints and other elements of our iFit technology platform. 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 have 87 employees engaged in the sales and marketing of our products in the United States, Germany and the United Kingdom to orthopedic surgeons, hospitals and other medical facilities and patients. For the year ended December 31, 2014 we generated revenue of

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$48.2 million from product sales, representing a 39% increase over the prior year. For the three months ended March 31, 2015, we generated revenue of $14.7 million from product sales, representing a 36% increase over the three months ended March 31, 2014.

Market opportunity

Osteoarthritis is the principal condition that leads to joint replacement surgery. An estimated 27 million people in the United States and 630 million people worldwide suffer from osteoarthritis. Compelling demographic trends, such as the growing population of aging yet active individuals and rising rates of obesity, are expected to be key drivers in the continued growth of osteoarthritis occurrence. The National Institutes of Health, or NIH, projects that by 2030, approximately 70 million people in the United States will be 65 years or older and at high risk of developing osteoarthritis. According to the Orthopaedic Industry Annual Report published in March 2015 by Orthoworld Inc., or the 2014 Orthoworld Report, worldwide sales of joint replacement products, including replacements for knees, hips, shoulders, elbows, wrists, ankles and digits outside of trauma, exceeded $15.4 billion in 2014 and are expected to grow to approximately $18 billion by the end of 2020.

Clinical shortcomings with off-the-shelf knee implants

Manufacturers of traditional knee replacement implants offer products with a limited range of sizes and geometries, which we refer to as off-the-shelf implants. Off-the-shelf implants are not designed to restore a particular patient's unique anatomy and are not customized to fit an individual patient's knee. As a result, during a knee replacement procedure, the surgeon has to fit the patient's soft tissue, bones and cartilage to the fixed dimensions of the implant through an iterative process of sizing and positioning. This entails removing bone, performing bone cuts and shaping the residual bone to the implant. Surgeons often have to make compromises on implant fit, rotation and alignment because they are limited by the size and shape of the implant. These compromises can cause residual pain and functional limitations after surgery, which we believe contribute to patient dissatisfaction. Our summary of one study indicates that approximately one in five patients who receives an off-the-shelf total knee replacement is not satisfied with the results. See "Business Industry Background Knee implants" for a description of our summary of this study.

In an effort to overcome the shortcomings associated with off-the-shelf implants, manufacturers have focused on improving traditional knee replacement in various ways, including the use of patient-specific instrumentation, or PSI, and robotic assistance and offering an increased range of sizes. We believe, however, that these efforts do not fully address the needs of patients, surgeons and hospitals.

The ConforMIS Solution: One Patient, One Implant

We believe our customized joint replacement products and proprietary technology create an opportunity to disrupt the large, existing market for orthopedic implants. Based on clinical data developed independently by orthopedic surgeons comparing our iTotal CR to off-the-shelf total knee replacement implants, as well as our own research and the common approach we employ in the design and manufacture of all of our products, we believe that our customized knee replacement implants offer significant benefits to the patient, the surgeon and the hospital that are not afforded by off-the-shelf implants.

For the patient. We believe that our individualized approach offers better clinical outcomes when compared to off-the-shelf implants based on the following measures:

Better fit. We design our customized knee implants to replicate the patient's own native anatomy. As a result, we believe that our implants fit better.

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Faster recovery. We believe an individual fit requires less bone and soft tissue removal by the surgeon, and therefore shortens recovery times.

Better function. We design our customized knee implants to follow the particular shape and contour of the patient's knee. As a result, we believe our implants offer an increased potential for a knee that moves more naturally and is more stable.

Greater patient satisfaction. We believe our implants offer patients greater overall satisfaction with the results of their knee replacement.

For the surgeon. We believe that the combination of the use of our iJigs with our customized knee replacement implants enables a more accurate, reproducible and simplified surgical procedure by reducing the number of required steps and increasing the precision of the placement of the implant.

For the hospital. We believe that our customized implants and iFit technology platform provide economic advantages for hospitals by:

improving patient recovery times, reducing blood loss and reducing adverse event rates at discharge;

reducing the costs associated with maintaining and sterilizing large numbers of reusable instruments; and

improving operating room turnaround times with the potential for more procedures to be completed within the same amount of time and for the hospital to generate additional revenue.

Our products

Knee replacement products

All of our knee replacement products have been cleared by the FDA under the premarket notification process of Section 510(k) of the FDCA and have received certification to CE Mark.

iTotal CR: the only cruciate-retaining, customized total knee replacement product on the market. We introduced the iTotal CR in May 2011 and launched new generations in each of 2012 and 2013.

iTotal PS: the only posterior cruciate ligament substituting, customized total knee replacement product on the market. We initiated a limited launch of the iTotal PS in the United States in February 2015, which we expect will continue into 2016.

iUni G2: the only customized unicompartmental knee replacement product on the market for treatment of the medial or lateral compartment of the knee. We first launched the iUni in June 2007 and launched new generations of the product in each of 2009 and 2012.

iDuo G2: the only customized bicompartmental knee replacement product on the market. The iDuo is a partial knee replacement implant for patients with osteoarthritis of the patellofemoral compartment of the knee and either the medial or lateral compartment of the knee. We first launched the iDuo in December 2007 and have launched new generations of the product in each of 2010 and 2012.

Hip replacement product candidate

iTotal Hip: our customized total hip replacement implant currently in development. We expect to file with the FDA for marketing clearance for our iTotal Hip in 2015 and expect that iTotal Hip will be our next major product launch after iTotal PS.

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Proprietary iJigs

Our iJigs are customized, single-use, patient-specific instruments. The iJigs we deliver with our joint replacement products include the guides and instruments the surgeon requires to remove the bone and soft tissue necessary to fit our customized implants to the patient.

Our strategy

Our objective is for our customized implants to become the standard of care for orthopedic joint replacement surgery. We believe that our iFit Image-to-Implant technology platform will enable us to offer a wide variety of customized joint replacement implants with superior performance that offer key clinical and economic benefits over off-the-shelf implants. Key elements of our strategy to achieve our objective are to:

- Broaden our product portfolio by launching additional customized orthopedic implants
- Expand our sales efforts to drive adoption of our products
- Establish the clinical and economic benefits of our products and technologies
- Expand our digitally driven, just-in-time manufacturing processes as a source of competitive advantage
- Enhance our patent portfolio and continue to exploit our patent position

Risks associated with our business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks include the following:

- We have incurred losses in the past, expect to incur losses for at least the next several years and may never achieve profitability.
- 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 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.
- 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 our iTotal Hip replacement product, which is currently in development. To date, we have obtained regulatory clearance for our products in the United States and outside 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 or in most jurisdictions outside the United States for additional knee products or iTotal Hip. However, to date, the regulatory agencies in the European Union, or 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.

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

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Surgeons, hospitals and other medical facilities 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 may not be successful in the development of, regulatory clearance process for or commercialization of additional products.

If we are unable to continue to develop additional 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.

If surgeons, hospitals and other medical facilities are unable to obtain favorable reimbursement rates from third-party payors for procedures involving use of our new 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.

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.

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

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

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.

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 company

Our company was formed as ConforMIS, Inc., a Delaware corporation, on March 26, 2004. Our principal executive offices are located at 28 Crosby Drive, Bedford, Massachusetts 01730, and our telephone number is (781) 345-9001. Our website address is www.conformis.com. The information contained on, or that can be accessed through, our website is not a part of, and is not incorporated into, this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

iFit® Image-to-Implant®, iTotal®, iUni®, iDuo® and iView® are our registered trademarks. The other trademarks, trade names and service marks appearing in this prospectus are the property of the respective owners. We do not intend our use or display of other companies' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

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Implications of being an emerging growth company

As a company with less than $1 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may remain an emerging growth company until the end of the 2020 fiscal year. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure and other requirements that are applicable to other public companies that are not emerging growth companies. In particular, in this prospectus, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

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THE OFFERING

Common stock offered by us	9,000,000 shares
Common stock to be outstanding after this offering	39,086,637 shares
Option to purchase additional shares	The underwriters have an option for a period of 30 days to purchase up to 1,350,000 additional shares of our common stock.
Use of proceeds	We estimate that the net proceeds from our issuance and sale of 9,000,000 shares of our common stock in this offering will be approximately $121 million, based on the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that the net proceeds from this offering will be approximately $140 million. We intend to use the net proceeds of this offering as follows: approximately $9 million to purchase and install capital equipment to expand our manufacturing capacity; approximately $59 million to expand and support our sales and marketing efforts; and approximately $26 million to fund research, development and clinical activities. The remaining proceeds will be used for working capital and other general corporate purposes. See "Use of Proceeds" for more information.
Risk factors	You should read the "Risk Factors" section starting on page 12 of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
NASDAQ Global Select Market symbol	"CFMS"

The number of shares of our common stock to be outstanding after this offering is based on the following:

4,345,755 shares of our common stock outstanding as of May 31, 2015;

25,527,505 additional shares of our common stock that will be issued upon the automatic conversion of all outstanding shares of our preferred stock upon the closing of this offering;

9,941 additional shares of common stock that will be issued upon the assumed net exercise of warrants to purchase our capital stock that would otherwise expire upon the closing of this offering, which we refer to as the net exercise warrants, and which consist of warrants to purchase:

69,772 shares of our Series D preferred stock at an exercise price of $6.00 per share; and

4,166 shares of our common stock at an exercise price of $4.32 per share;

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based on the initial public offering price of $15.00 per share, and we refer to the foregoing as the assumed warrant exercises; and

203,436 additional shares of our common stock that will be issued for no additional consideration upon the closing of this offering in exchange for surrender of warrants to purchase an aggregate of 406,874 shares of our Series D preferred stock, which we refer to as the Series D warrant exchange.

The number of shares of our common stock to be outstanding after this offering excludes:

684,334 shares of our common stock issuable upon the exercise of warrants outstanding as of May 31, 2015, at a weighted average exercise price of $10.08 per share other than shares issuable in connection with the assumed warrant exercises and the Series D warrant exchange;

33,481 shares of common stock issuable upon exercise of warrants to purchase common stock, at an exercise price of $8.96 per share, that we will be required to issue in the event we borrow a second $10 million term loan under our credit facility with Silicon Valley Bank and Oxford Finance LLC;

5,622,475 shares of our common stock issuable upon the exercise of stock options outstanding as of May 31, 2015, at a weighted average exercise price of $5.29 per share;

256,013 shares of our common stock available for future issuance under our 2011 stock incentive plan as of May 31, 2015; and

an additional 2,000,000 shares of our common stock that will become available for future issuance under our 2015 stock incentive plan in connection with the closing of this offering.

Unless otherwise indicated, all information in this prospectus reflects and assumes the following:

the automatic conversion of all outstanding shares of our preferred stock into 25,527,505 shares of our common stock upon the closing of this offering;

the assumed warrant exercises occur upon the closing of this offering;

the Series D warrant exchange occurs upon the closing of this offering;

other than the assumed warrant exercises and the Series D warrant exchange, no exercise of the outstanding options or warrants described above;

warrants outstanding as of May 31, 2015, to purchase 919,802 shares of our Series E-1 and Series E-2 preferred stock at an exercise price of $8.00 per share that expire upon the closing of this offering instead become exercisable for 459,887 shares of our common stock at an exercise price of $16.00 per share upon the closing of this offering and expire unexercised, based on the initial public offering price of $15.00 per share;

warrants outstanding as of May 31, 2015, to purchase 682,665 shares of our Series D preferred stock at an exercise price of $6.00 per share instead become exercisable for 341,331 shares of our common stock at an exercise price of $12.00 per share

upon the closing of this offering;

warrants to purchase 285,714 shares of our Series C preferred stock at an exercise price of $3.50 per share are exchanged for warrants to purchase 142,857 shares of our common stock at an exercise price of $7.00 per share, which we refer to as the Series C warrant exchange;

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the restatement of our certificate of incorporation and the amendment and restatement of our bylaws upon the closing of this offering; and

no exercise by the underwriters of their option to purchase up to 1,350,000 additional shares.

In addition, unless otherwise indicated, all information in this prospectus gives effect to a one-for-two reverse stock split of our common stock that became effective on June 16, 2015.

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SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following summary consolidated financial data together with the more detailed information contained in "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the accompanying notes thereto appearing elsewhere in this prospectus. We have derived the statements of operations data for the years ended December 31, 2013 and 2014 from our audited consolidated financial statements appearing elsewhere in this prospectus. We have derived the statements of operations data for the three months ended March 31, 2014 and 2015 from our unaudited consolidated financial statements appearing elsewhere in this prospectus. Historical results are not indicative of the results to be expected in the future, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period.

(in thousands, except share and per share data)	Years ended December 31, 2013	2014	Three months ended March 31, 2014 (unaudited)	2015 (unaudited)
Consolidated statements of operations data:				
Revenue	$ 34,597	$ 48,186	$ 10,799	$ 14,700
Cost of revenue	27,283	30,638	7,512	9,388
Gross profit	7,314	17,548	3,287	5,312
Operating expenses:				
Sales and marketing	26,149	31,103	8,379	9,579
Research and development	13,779	15,107	3,578	4,016
General and administrative	14,693	16,763	3,948	5,780
Total operating expenses	54,621	62,973	15,905	19,375
Loss from operations	(47,307)	(45,425)	(12,618)	(14,063)
Other income and expenses				
Interest income	89	104	25	39
Interest expense	(642)	(360)	(52)	(223)
Total other expenses	(553)	(256)	(27)	(184)
Loss before income taxes	(47,860)	(45,681)	(12,645)	(14,247)
Income tax provision	29	41	8	10
Net loss	$ (47,889)	$ (45,722)	$ (12,653)	$ (14,257)
Net loss per share applicable to common stockholders basic and diluted(1)	$ (11.98)	$ (10.78)	$ (3.04)	$ (3.32)
Weighted-average number of common shares used in net loss per share applicable to common stockholders basic and diluted(1)	3,996,867	4,239,564	4,165,760	4,296,613
Pro forma net loss per share applicable to common stockholders basic and diluted (unaudited)(1)(2)		$ (1.53)		$ (0.47)

Pro forma weighted average number of common shares outstanding basic and diluted (unaudited)(1)(2)	29,980,446	30,037,495

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(in thousands)	March 31, 2015 Actual (unaudited)	Pro forma(2)	Pro forma as adjusted(3)
Consolidated balance sheet data:			
Cash and cash equivalents	$ 22,939	$ 23,355	$ 144,637
Working capital	31,065	31,481	152,763
Total assets	60,705	61,121	182,403
Long-term debt, including current portion	10,560	10,560	10,560
Total stockholders' equity	36,781	37,197	158,479

(1) See Note B in the notes to our consolidated financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net loss per share applicable to common stockholders.

(2) The pro forma balance sheet data give effect to (a) the exercise of warrants to purchase 69,425 shares of our preferred stock since March 31, 2015, (b) the automatic conversion of all outstanding shares of our preferred stock into 25,527,505 shares of common stock, (c) the assumed warrant exercises and (d) the Series D warrant exchange.

(3) The pro forma as adjusted balance sheet data give further effect to our issuance and sale of 9,000,000 shares of common stock in this offering (assuming no exercise by the underwriters of their option to purchase additional shares) at the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

In connection with the closing of this offering, the holders of the net exercise warrants have the option to net exercise their warrants or exercise their warrants for cash at various exercise prices ranging from $4.32 to $12.00 per common share. In the event that all the net exercise warrants are exercised with cash consideration instead of being net exercised upon the closing of this offering, an additional 29,110 shares of our common stock would be outstanding as of the closing. In addition, the pro forma and pro forma as adjusted amount of each of cash and cash equivalents, working capital and total stockholders' equity would increase by $0.4 million.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. Before you decide to invest in our common stock, you should consider carefully the risks described below, together with the other information contained in this prospectus, including our consolidated financial statements and the related notes appearing at the end of this prospectus. We believe the risks described below are material to us as of the date of this prospectus. 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. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

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 $47.9 million for the year ended December 31, 2013, $45.7 million for the year ended December 31, 2014, $14.3 million for the three months ended March 31, 2015, and $12.7 million for the three months ended March 31, 2014. As of March 31, 2015, we had an accumulated deficit of $282.4 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, following this offering, 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 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;
- servicing our indebtedness under our existing credit facilities; and
- preparing, filing and prosecuting patent applications, and maintaining and enforcing our intellectual property rights and position.

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In addition, following this offering, 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 following this offering our principal sources of funds will be revenue generated from the sales of our products, borrowings under our credit facilities and revenues that we may generate in connection with licensing our intellectual property. Our credit facility with Silicon Valley Bank and Oxford Finance LLC, referred to as the SVB/Oxford Agreement, is our only committed external source of funds. In November 2014, we borrowed the first of two $10 million term loans under the SVB/Oxford Agreement. We are eligible to borrow a second term loan in a principal amount of $10 million on or prior to November 7, 2015 upon meeting certain conditions, including our being able to make certain agreed upon representations and warranties to the lenders and a determination by the lenders, in their sole discretion, that there has been no occurrence of any material adverse change, as defined in the SVB/Oxford Agreement, or any material deviation from the annual financial projections provided by us and accepted by the lenders. There can be no assurance that we will be able to satisfy these conditions or borrow the second $10 million term loan. For further information regarding this facility, see "Management's Discussion and Analysis of Financial Conditions and Results of Operations Credit facilities SVB/Oxford."

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, including the funds required to pay our existing indebtedness at maturity. We may not be able to obtain additional financing on terms favorable to us, or at all. In addition, the covenants, pledge of our assets as collateral and negative pledge with respect to our intellectual property under the SVB/Oxford Agreement could limit our ability to obtain additional debt financing. To the extent that we raise additional capital through the future sale of equity or 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;
- 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;

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implement and successfully execute our business and marketing strategy;

respond effectively to competitive pressures 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.

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.

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, iTotal PS, which we are in the process of launching commercially on a limited basis, and expect to introduce our first hip replacement product, the iTotal Hip, for which we expect to file for marketing clearance in 2015 with the FDA. 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 on the timelines that we expect to, or at all. 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.

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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. See "Business Competition." 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;
- 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

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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.

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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:

- 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;
- 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 only one clinical study, which was presented as an abstract at an industry conference and not in a peer-reviewed journal, 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, but not cruciate-retaining 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

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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 197 patients for which we provided financial support, the 2.55% 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. See "Business Clinical studies" for additional information on this multi-center study. By comparison, the rate of MUA reported in a separate multi-center 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.

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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, including iTotal PS and iTotal Hip, 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;

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.

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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, 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 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 PS and iTotal Hip, as unproven or experimental, and on that basis may deny coverage of procedures involving use of our products. 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.

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 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.

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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

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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 52% of our total revenue from sales of our products in the United States for the year ended December 31, 2014 and approximately 51% of our total revenue from sales of our products in the United States for the year ended December 31, 2013. We did not generate any revenue from sales of our products by independent sales representatives outside the United States in the years ended December 31, 2014 and December 31, 2013. 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 year ended December 31, 2014 and approximately 5% of our total revenue from sales of our products outside the United States for the year ended December 31, 2013. We did not generate any revenue from sales of our products to distributors in the United States in the years ended December 31, 2014 and December 31, 2013. 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.

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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 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

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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 March 31, 2015, we had $10.0 million of outstanding term loans under the SVB/Oxford Agreement and $0.7 million of outstanding term loans under our credit facility with the Massachusetts Development Finance Agency, referred to as the MDFA facility. We could in the future incur additional indebtedness under the SVB/Oxford Agreement, including, subject to an available borrowing base, under a committed $5.0 million revolving line of credit, referred to as the Revolving Line, and, upon meeting certain conditions, under a $10.0 million commitment for additional term loans, or additional indebtedness from other lenders. See "Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity, capital resources and plan of operations Credit facilities" for a description of our outstanding credit facilities.

Our obligations under the SVB/Oxford Agreement and 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. In addition, indebtedness under the Revolving Line bears interest at a variable rate, making us vulnerable to increases in the market rate of interest. If the market rate of interest increases substantially, we will have to pay additional interest on this indebtedness, which would reduce cash available for our other business needs.

Our obligations under the SVB/Oxford Agreement are secured by a security interest over substantially all of our assets and the assets of our wholly owned subsidiary ImaTx, Inc., or ImaTx, other than intellectual property, with respect to which we and ImaTx granted a negative pledge. Moreover, the MDFA facility is secured by a lien over certain of our equipment. The security interests granted over our assets and the negative pledge with respect to our intellectual property could limit our ability to obtain additional debt financing. In addition, the SVB/Oxford Agreement and the documentation governing the MDFA facility contain negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions, incurring indebtedness or liens, paying dividends or making investments and certain other business transactions. Future debt securities or other financing arrangements could contain similar or more restrictive negative covenants.

We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our debt arrangements. Our obligations under the agreements governing our indebtedness are subject to acceleration upon the occurrence of specified events of default, including payment defaults or the occurrence of a material adverse change in our business,

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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.

Our outstanding indebtedness combined with our other financial obligations and contractual commitments, including any additional indebtedness that we 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. 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.

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

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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 manufacture a portion of our products at our facilities in Burlington, Bedford and Wilmington, Massachusetts. We are in the process of transitioning our manufacturing operations at our Burlington facility to our Wilmington facility and expect to complete this transition by August 2015, when we intend to vacate our Burlington facility. We may encounter delays as part of this transition and may have limited manufacturing capacity in the event that we are not able to complete the transition on a timely basis. Any limitation in our manufacturing capacity could adversely affect our results of operations.

We plan to continue the build out of our manufacturing capabilities at our Wilmington facility using a portion of the net proceeds of this offering. All manufacturing processes in our Bedford, Burlington 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 are in the process of validating our manufacturing processes for implant components and instrumentation manufactured at our new Wilmington facility. Delays in validation or FDA registration of our new facilities could impact our ability to grow our business in the future.

Our current and planned future products are complex and require the integration of a number of separate components and processes. To become profitable, we must manufacture our products in increased quantities in compliance with regulatory requirements and at an acceptable cost. Increasing our capacity to manufacture our products on this scale will require us to introduce new manufacturing processes, including direct metal laser sintering, or DMLS, 3D printing of metal implant components and vertical integration of the manufacturing process by performing machining, polishing and other finishing services in-house, and to improve internal efficiencies. To date, we have not used 3D printing technology to manufacture commercially the metal implants that are used in our joint replacement systems. In addition, we have limited commercial manufacturing experience with respect to our iTotal PS knee and no commercial manufacturing experience yet with respect to our iTotal Hip replacement products.

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

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

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

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maintaining quality control and assurance;

maintaining component availability;

maintaining adequate control policies and procedures;

hiring and retaining qualified personnel; and

complying with state, federal and foreign regulations.

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

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 raw materials, including polymer powders that currently are used, and metal powders we intend to use, in our 3D printing and manufacturing processes from a limited number of third-party suppliers. 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.

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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; and
- disruptions in the supply chain due to weather conditions and natural disasters affecting suppliers, our employees, and freight carriers.

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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 the United Kingdom, Germany, Austria, Ireland, Switzerland, Hong Kong and Singapore. We expect that our international activities will increase over

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the foreseeable future as we continue to pursue opportunities in international markets. During each of the years ended December 31, 2013 and 2014, approximately 29% of our revenue was attributable to our international customers, and as of December 31, 2014, approximately 6% of our employees were located outside the United States. For the three months ended March 31, 2015, approximately 30% of our revenue was attributable to our international customers, and as of March 31, 2015, approximately 6% 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., Canadian, 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;

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

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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.

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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 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. For more information on the revenue share arrangements, see "Certain Relationships and Related-Persons Transactions Revenue share agreement with Dr. Lang."

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

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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 partes 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.

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

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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.

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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.

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.

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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 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.

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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.

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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 regulatory approval

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;

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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.

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 application 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

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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:

- 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 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. 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.

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

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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. The conduct of clinical studies to obtain clinical data that might be required as part of the described clinical evaluation process can be expensive and time-consuming. To date, we have not been required to conduct any of these clinical studies to obtain clinical data as part of the clinical evaluation process.

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 postmarketing 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 Certificate of Conformity enabling us to affix the CE Mark to a product and to sell our product in the EEA, 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 of Conformity 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. Moreover, each CE Certificate of Conformity is valid for a maximum of five years, but more commonly three years. Our CE Certificates of Conformity are valid through August 5, 2016 for our iTotal CR product, February 12, 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 of Conformity. There may be delays in the renewal of the CE Certificate of Conformity 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 of Conformity.

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

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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 II products as 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 onerous 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

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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.

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. 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.

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, 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;

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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 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;

fines, restitution or disgorgement of profits or revenues;

suspension or withdrawal of regulatory clearance or approval;

damage to relationships with any potential collaborators;

unfavorable press coverage and damage to our reputation;

refusal to permit the import or export of our products;

product seizure; or

injunctions or the imposition of civil or criminal penalties.

We may fail to obtain or maintain foreign regulatory approvals to market our products in other countries.

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.

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 restrictions or withdrawal from the market.

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

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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 of Conformity. 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 of Conformity, 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. While all of our previous inspections have resulted in no significant observations, 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 February 2015. 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.

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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.

Under the FDA medical device report, 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, and 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.

In the future, our products may be subject to 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. We have experienced limited recalls in the past, related to manufacturing defects, labeling updates and packaging inconsistencies. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our international distributors 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

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are also required to follow detailed recordkeeping requirements for all company-initiated medical device corrections and removals and to report such corrective and removal actions to the FDA if they are carried out in response to a risk to health and have not otherwise been reported under the MDR regulations. We may initiate voluntary recalls involving our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall 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.

We may be subject to enforcement action if we engage in improper marketing or promotion of our products.

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

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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;
- 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 fiscal 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

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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

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. 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. We are subject to this excise tax and during the year ending December 31, 2014, we incurred $0.7 million in tax expense associated with the medical device tax in the United States, which is included in general and administrative expense.

We are subject to federal and state laws prohibiting "kickbacks" and false and fraudulent claims which, if violated, could subject us to substantial penalties. Additionally, any challenges to or investigation into our practices under these laws could cause adverse publicity and could be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Our relationships with surgeons, hospitals and other medical facilities, group purchasing organizations and our international distributors are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including significant monetary penalties and, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, including claims that are made in violation of the federal healthcare Anti-Kickback Statute;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

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the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections;

the federal Foreign Corrupt Practices Act of 1977, which prohibits corrupt payments, gifts or transfers of value to foreign officials; and

foreign and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the PPACA, among other things, amended the intent requirements of the federal Anti-Kickback Statute and the criminal statute governing healthcare fraud. A person or entity can now be found guilty of violating the Anti-Kickback Statute and the federal criminal healthcare fraud statute without actual knowledge of the statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim that included items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. Possible sanctions for violation of laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions. Moreover, while we do not submit claims and our customers make the ultimate decision on how to submit claims, from time-to-time, we may provide generally applicable information regarding reimbursement from publicly available sources to our customers, including hospitals, surgery centers and physicians. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend such actions, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

To enforce compliance with the federal laws, the DOJ has recently increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from a company's business. Additionally, settlements with the DOJ or other law enforcement agencies have forced healthcare providers to agree to additional onerous compliance and reporting requirements as part of consent decrees or corporate integrity agreements. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

On February 8, 2013, the Centers for Medicare & Medicaid Services, or CMS, released its final rule, commonly known as the Physician Payment Sunshine Act, implementing certain provisions of the PPACA imposing new reporting requirements on device manufacturers for payments by them and in some cases their distributors to physicians and teaching hospitals, as well as ownership and investment interests held by physicians. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Device manufacturers were required to begin collecting data on August 1, 2013 and to submit reports to CMS beginning March 31, 2014 and by the 90th day of each subsequent calendar year. In addition, CMS estimates that approximately 1,000 device and medical supply companies will be required to comply with the disclosure requirements and that the average cost per entity will be approximately $170,000 in the first year. The Physician Payment Sunshine Act was only recently enacted and

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additional questions surrounding implantation remain to be resolved by CMS. In light of this regulatory uncertainty, we may not, in the view of CMS, successfully report all transfers of value by us and our independent sales representatives and distributors, and any failure to successfully report could result in significant fines and penalties.

In addition, the scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

Laws and regulations governing our foreign operations, including anti-corruption laws, 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.

We must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we operate or plan to operate outside of the United States, including anti-corruption laws such as the FCPA, U.K. Bribery Act 2010, or the Bribery Act, and other anti-corruption laws. The FCPA, the Bribery Act and these other anti-corruption laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. 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 company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA and Bribery Act is expensive and difficult, particularly in countries in which corruption is a recognized problem, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, Bribery Act or local anti-corruption laws. In addition, the FCPA presents particular challenges in the medical device industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical studies and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act or other legal requirements. If we are not in compliance with the FCPA, the Bribery Act and other anti-corruption laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the FCPA, the Bribery Act or other anti-corruption laws or U.S., U.K. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. To comply with these laws will require additional resources, and these laws may preclude

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us from developing, manufacturing or selling certain product candidates and products outside of the United States, which could limit our growth potential and increase our development costs.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing the generation, handling, use, storage, treatment, manufacture, transportation and disposal of, and exposure to, hazardous materials and wastes, as well as laws and regulations relating to occupational health and safety. Our operations involve the use of hazardous materials, including chemicals, and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials or wastes. In the event of contamination or injury resulting from hazardous materials or wastes either at our sites or third-party sites, we could be held liable for any resulting damages, and any liability could exceed our resources.

Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work related injuries, this insurance may not provide adequate coverage against potential liabilities. We also could incur significant costs associated with civil or criminal fines and penalties.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

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. Healthcare providers, including our customers, are subject to these regulations, and we contractually agree to obligations of confidentiality with respect to personal health information we receive as part of our business operations. 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.

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Risks related to our common stock and this offering

If you purchase shares of common stock in this offering, you will suffer immediate dilution in the book value of your investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. Based on the initial public offering price of $15.00 per share, you will experience immediate dilution of $10.99 per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the initial public offering price. Purchasers of common stock in this offering will have contributed approximately 29% of the aggregate price paid by all purchasers of our stock and will own approximately 23% of our common stock outstanding after this offering, excluding any shares of our common stock that they may have acquired prior to this offering. Furthermore, if the underwriters exercise their option to purchase additional shares or our previously issued options and warrants to acquire common stock at prices below the initial public offering price are exercised, you will experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see "Dilution."

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. Although our common stock has been approved for listing on the NASDAQ Global Select Market, an active trading market for our shares may never develop or, if developed, be maintained following this offering. If an active market for our common stock does not develop or is not maintained, it may be difficult for you to sell shares you purchase in this offering 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 in this offering.

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 the initial public offering 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;

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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.

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 CT scans 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;

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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.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. See "Use of Proceeds." The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business and cause the price of our common stock to decline. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

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. After this offering, we will have 39,086,637 shares of common stock outstanding based on the 30,086,637 shares outstanding as of May 31, 2015 after giving effect to the conversion of all outstanding shares of our preferred stock into 25,527,505 shares of our common stock upon the closing of this offering, the assumed warrant exercises and the Series D warrant exchange. Of these shares, the 9,000,000 shares sold by us in this offering may be resold in the public market immediately, unless purchased by our affiliates. The remaining 30,086,637 shares are currently restricted under securities laws or as a result of lock-up or other agreements, but will be able to be sold after this offering as described in the "Shares Eligible for Future Sale" and "Underwriting" sections of this prospectus. Moreover, upon the closing of the offering contemplated by the registration statement of which this prospectus forms a part, pursuant to the terms of the Registration Rights Agreement described under "Description of Capital Stock Registration rights," subject to the lock-agreements described under "Shares Eligible for Future Sale Lock-up agreements," holders of an aggregate of 25,527,505 shares of our common stock that will be issued upon the conversion of our preferred stock, which we refer to as registrable shares, will have the right to require us to register these registrable shares under the Securities Act no earlier than 180 days after the closing of the offering contemplated by the registration statement of which this prospectus forms a part, and to participate in future registrations of securities by us, under the circumstances and subject to the conditions described under "Description of Capital Stock

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Registration rights." In addition, subject to the lock-up agreements described under "Shares Eligible for Future Sale Lock-up agreements," upon the closing of the offering contemplated by the registration statement of which this prospectus forms a part, the holders of warrants to purchase an aggregate of 684,334 shares of our common stock, assuming conversion of our preferred stock into common stock upon the closing of the offering, the assumed warrant exercises and the Series D warrant exchange, will have the right to have the shares of common stock issuable upon exercise of such warrants be treated as registrable shares and to require us to register these registrable shares under the Securities Act no earlier than 180 days after the closing of the offering contemplated by the registration statement of which this prospectus forms a part, and to participate in future registrations of securities by us, under the circumstances and subject to the conditions described under "Description of Capital Stock Registration rights." We also plan to register all 7,878,488 shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to significantly influence all matters submitted to stockholders for approval.

Upon the closing of this offering, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering and their affiliates will, in the aggregate, beneficially own shares representing approximately 40.46% of our capital stock (or 39.20% if the underwriters exercise their option to purchase additional shares in full). 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, 2014, we had federal net operating loss, or NOL, carryforwards of $229 million and state NOL carryforwards of $117 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, including as a result of the

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consummation of this offering. 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 that will become effective upon the closing of this offering 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.

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Our restated certificate of incorporation that will become effective upon the closing of this offering 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 that will become effective upon the closing of this offering 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 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, the terms of our SVB/Oxford Agreement preclude us from paying dividends, and 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 fiscal year in which we have total annual gross revenues of $1 billion or more; (2) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (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 are permitted and plan 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. In this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related

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information that would be required if we were not an EGC. 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.

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 Select 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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "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 for our current and future products, including our iTotal CR, our iTotal PS and, if we received 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;
- 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;

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

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

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

our expectations related to the use of proceeds from this offering; 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 prospectus, 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 prospectus, the documents that we reference in this prospectus and the documents that we have filed as exhibits to the registration statement of which this prospectus is a part 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.

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USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 9,000,000 shares of our common stock in this offering will be approximately $121 million, based on the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that the net proceeds from this offering will be approximately $140 million.

As of March 31, 2015, we had cash and cash equivalents of $22.9 million. We currently estimate that we will use the net proceeds from this offering as follows:

- approximately $9 million to purchase and install capital equipment to expand manufacturing capacity;
- approximately $59 million to expand and support our sales and marketing efforts;
- approximately $26 million to fund research, development and clinical activities; and
- the remaining proceeds for working capital and other general corporate purposes.

We believe opportunities may exist from time to time to expand our current business through acquisitions or in-licenses of complementary products or technologies or acquisitions of companies with complementary products or technologies. While we have no current agreements, commitments or understandings for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.

The expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors including the degree and rate of market acceptance of, and the amount of revenue derived from, our products, including our iTotal PS product which is currently in limited commercial launch, the timing of U.S. and EU regulatory clearance and commercial launch of our iTotal Hip, the progress of our plans to expand and further vertically integrate our manufacturing processes and facilities and the size, scope and timing of any additional research and development efforts and clinical studies that we may decide to pursue for our current products or future product candidates. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

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DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay any cash dividends to the holders of our common stock in the foreseeable future. Our ability to pay dividends on our common stock is prohibited by the covenants of our debt facilities with Silicon Valley Bank and Oxford Financial LLC and with the Massachusetts Development Finance Agency and may be further restricted by the terms of any of our future indebtedness.

INDUSTRY AND OTHER DATA

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties, including content republished with permission from ORTHOWORLD®, a specialized publishing firm serving the global orthopedic market. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2015 on:

- an actual basis, except to the extent it has been adjusted to give effect to a one-for-two reverse split of our common stock that became effective on June 16, 2015;
- a pro forma basis giving effect to the following:
  - the exercise of warrants to purchase 69,425 shares of our preferred stock since March 31, 2015;
  - the conversion of all outstanding shares of our preferred stock into 25,527,505 shares of our common stock;
  - the assumed warrant exercises;
  - the Series D warrant exchange; and
  - the filing of our restated certificate of incorporation, upon the closing of this offering.
- a pro forma as adjusted basis giving additional effect to the sale of 9,000,000 shares of our common stock (assuming no exercise by the underwriters of the option to purchase additional shares) offered in this offering, at the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

See "Prospectus Summary The Offering" for a description of the assumed warrant exercises and the Series D warrant exchange.

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You should read the following table in conjunction with our consolidated financial statements and related notes, "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus.

	As of March 31, 2015		
(in thousands, except share and per share data)	**Actual (unaudited)**	**Pro forma**	**Pro forma as adjusted**
Cash and cash equivalents	$ 22,939	$ 23,355	$ 144,637
Stockholders' equity:			
Convertible preferred stock, $0.00001 par value; 53,496,241 shares authorized, 50,985,652 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted			
Preferred stock, $0.00001 par value; no shares authorized, issued or outstanding, actual; 5,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted			
Common stock, $0.00001 par value per share; 80,000,000 shares authorized, 4,314,338 shares issued and outstanding, actual; 200,000,000 shares authorized, 30,055,220 shares issued and outstanding, pro forma; 200,000,000 shares authorized, 39,055,220 shares issued and outstanding, pro forma as adjusted			
Additional paid-in capital	319,634	320,050	441,332
Accumulated deficit	(282,353)	(282,353)	(282,353)
Accumulated other comprehensive loss	(500)	(500)	(500)
Total stockholders' equity	36,781	37,197	158,479
Total capitalization	$ 36,781	$ 37,197	$ 158,479

The table above does not include:

684,334 shares of our common stock issuable upon the exercise of warrants outstanding as of March 31, 2015, at a weighted average exercise price of $10.08 per share;

459,887 shares of our common stock issuable upon the exercise of warrants outstanding as of March 31, 2015, to purchase 919,802 shares of our Series E-1 and E-2 preferred stock, at an exercise price of $8.00 per share, which expire upon the closing of this offering;

5,649,174 shares of our common stock issuable upon the exercise of stock options outstanding as of March 31, 2015, at a weighted average exercise price of $5.24 per share;

260,726 shares of our common stock available for future issuance under our 2011 stock incentive plan as of March 31, 2015; and

an additional 2,000,000 shares of our common stock that become available for future issuance under our 2015 stock incentive plan, in connection with the closing of this offering.

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DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma tangible book value per share of our common stock after this offering.

Our historical net tangible book value as of March 31, 2015 was $35.0 million, or $8.09 per share of our common stock. Historical net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by 4,314,338 shares of our common stock outstanding as of March 31, 2015.

Our pro forma net tangible book value as of March 31, 2015 was $35.3 million, or $1.17 per share of common stock. Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by the pro forma number of shares of our common stock outstanding on March 31, 2015, after giving effect to the following:

- the exercise of warrants to purchase 69,425 shares of our preferred stock;
- the automatic conversion of all outstanding shares of our preferred stock into 25,527,505 shares of our common stock upon the closing of this offering;
- the assumed warrant exercises; and
- the Series D warrant exchange.

After giving effect to our issuance and sale of 9,000,000 shares of common stock in this offering at the initial public offering price of $15.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, the pro forma net tangible book value as of March 31, 2015 would have been $156.6 million, or $4.01 per share. This represents an immediate increase in pro forma net tangible book value to existing stockholders of $2.84 per share. The initial public offering price per share will significantly exceed the pro forma net tangible book value per share. Accordingly, new investors who purchase shares of common stock in this offering will suffer an immediate dilution of their investment of $10.99 per share. The following table illustrates this per share dilution to the new investors purchasing shares of common stock in this offering without giving effect any exercise by the underwriters to purchase additional shares:

Initial public offering price per share		$ 15.00
Historical net tangible book value per share as of March 31, 2015	$ 8.09	
Decrease attributable to the conversion of outstanding preferred stock and warrants to purchase preferred stock	(6.92)	
Pro forma net tangible book value per share as of March 31, 2015	1.17	
Increase per share attributable to sale of shares of common stock in this offering	2.84	
Pro forma net tangible book value per share after this offering		$ 4.01
Dilution per share to new investors		$ 10.99

If the underwriters exercise their option to purchase additional shares in full, the pro forma net tangible book value will increase to $4.34 per share, representing an immediate increase to existing stockholders of $3.17 per share and an immediate dilution of $10.66 per share to new investors. If any shares are issued upon exercise of outstanding options or our outstanding warrants, you will experience further dilution.

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The following table summarizes, on a pro forma basis as of March 31, 2015, after giving effect to the exercise of warrants to purchase 69,425 shares of our preferred stock since March 31, 2015; to the automatic conversion of all of our outstanding shares of preferred stock into 25,527,505 shares of common stock upon the closing of this offering; the assumed warrant exercises; the Series D warrant exchange, the differences between the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid by existing stockholders and by new investors purchasing shares of common stock in this offering. The calculation below is based on the initial public offering price of $15.00 per share, before the deduction of underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares purchased		Total consideration		Average price per share
	Number	%	Amount	%	
Existing stockholders	30,055,220	77%	$ 329,984,529	71%	$ 10.98
New investors	9,000,000	23	135,000,000	29	$ 15.00
Total	39,055,220	100%	$ 464,984,529	100%	$ 11.91

The number of shares purchased from us by existing stockholders is based on 4,314,338 shares of our common stock outstanding as of March 31, 2015, after giving effect to the exercise of warrants to purchase 69,425 shares of our preferred stock since March 31, 2015; to the automatic conversion of all of our outstanding shares of preferred stock into 25,527,505 shares of common stock upon the closing of this offering; the assumed warrant exercises; the Series D warrant exchange; and excludes:

- 684,334 shares of our common stock issuable upon the exercise of warrants outstanding as of March 31, 2015, at a weighted average exercise price of $10.08 per share;
- 459,887 shares of our common stock issuable upon the exercise of warrants outstanding as of March 31, 2015, to purchase 919,802 shares of our Series E-1 and E-2 preferred stock, at an exercise price of $8.00 per share, which expire upon the closing of this offering; and
- 5,649,174 shares of our common stock issuable upon the exercise of stock options outstanding as of March 31, 2015, at a weighted average exercise price of $5.24 per share.

If the underwriters exercise their option to purchase additional shares in full:

- the percentage of shares of common stock held by existing stockholders will decrease to approximately 74.4% of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors will increase to 10,350,000, or approximately 25.6% of the total number of shares of our common stock outstanding after this offering.

Effective immediately upon closing of this offering, an aggregate of 2,256,013 shares of our common stock will be reserved for issuance under our 2015 stock incentive plan, assuming the number of shares available for issuance under our 2011 stock incentive plan, which become available for issuance under the 2015 stock incentive plan upon the closing of the offering, does not change following May 31, 2015, and this share reserve will also be subject to automatic annual increases in accordance with the terms of the 2015 stock incentive plan. Furthermore, we may choose to raise additional capital through the sale of equity or equity-linked securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that new equity awards are issued under our 2015 stock incentive plans or we issue additional shares of common stock or other equity or equity-linked securities in the future, there may be further dilution to investors participating in this offering.

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SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with our consolidated financial statements and accompanying notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. The selected consolidated financial data in this section are not intended to replace our consolidated financial statements and the related notes included elsewhere in this prospectus.

The selected consolidated statement of operations data for the years ended December 31, 2013 and 2014 and the selected consolidated balance sheet data as of December 31, 2013 and 2014 are derived from our audited consolidated financial statements appearing elsewhere in this prospectus. The selected consolidated statement of operations data for the three months ended March 31, 2014 and 2015 and the selected consolidated balance sheet data as of March 31, 2014 and 2015 are derived from our unaudited consolidated financial statements included elsewhere in this prospectus. The selected consolidated statement of operations data for the year ended December 31, 2012 and the selected consolidated balance sheet data as of December 31, 2012 are derived from our audited consolidated financial statements, which are not included in this prospectus. Our historical results are not necessarily indicative of the results that may be expected

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in the future, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period.

(in thousands, except share and per share data)	Years ended December 31,			Three months ended March 31,	
	2012	2013	2014	2014 (unaudited)	2015 (unaudited)
Consolidated statements of operations data:					
Revenue	$ 24,644	$ 34,597	$ 48,186	$ 10,799	$ 14,700
Cost of revenue	21,820	27,283	30,638	7,512	9,388
Gross profit	2,824	7,314	17,548	3,287	5,312
Operating expenses:					
Sales and marketing	26,070	26,149	31,103	8,379	9,579
Research and development	10,127	13,779	15,107	3,578	4,016
General and administrative	10,827	14,693	16,763	3,948	5,780
Total operating expenses	47,024	54,621	62,973	15,905	19,375
Loss from operations	(44,200)	(47,307)	(45,425)	(12,618)	(14,063)
Other income and expenses					
Interest income	126	89	104	25	39
Interest expense	(3,427)	(642)	(360)	(52)	(223)
Total other expenses	(3,301)	(553)	(256)	(27)	(184)
Loss before income taxes	(47,501)	(47,860)	(45,681)	(12,645)	(14,247)
Income tax provision		29	41	8	10
Net loss	$ (47,501)	$ (47,889)	$ (45,722)	$ (12,653)	$ (14,257)
Net loss per share applicable to common stockholders basic and diluted(1)	$ (13.48)	$ (11.98)	$ (10.78)	$ (3.04)	$ (3.32)
Weighted-average number of common shares used in net loss per share applicable to common stockholders basic and diluted(1)	3,523,466	3,996,867	4,239,564	4,165,760	4,296,613
Pro forma earnings (loss) per common share, basic and diluted (unaudited)			$ (1.53)		$ (0.47)
Weighted-average shares used to compute pro forma net earnings (loss) per common share, basic and diluted (unaudited)(1)(2)			29,980,446		30,037,495

(1) See Note B in the notes to our consolidated financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net (loss) per share applicable to common stockholders.

(2) The pro forma net loss per share applicable to common stockholders is computed using the weighted-average number of common shares outstanding after giving effect to (a) the exercise of warrants to purchase 69,425 shares of our preferred stock since March 31, 2015, (b) the automatic conversion of all outstanding shares of our preferred stock into 25,527,505 shares of common stock, (c) the assumed warrant exercises, and (d) the Series D warrant exchange.

(in thousands)	December 31, 2012	2013	2014	March 31, 2015 (unaudited)
Consolidated balance sheet data:				
Cash and cash equivalents	$ 39,734	$ 54,221	$ 37,900	$ 22,939
Working capital	37,122	54,277	45,036	31,065
Total assets	59,376	83,891	71,278	60,705
Long term debt, including current portion	7,456	3,111	10,620	10,560
Total stockholders' equity	43,095	68,960	49,827	36,781

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MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many important factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See "Special Note Regarding Forward-Looking Statements."

Overview

We are a medical technology company that uses our proprietary iFit Image-to-Implant technology platform to develop, manufacture and sell joint replacement implants that are individually sized and shaped, which we refer to as customized, to fit each patient's unique anatomy. The worldwide market for joint replacement products is approximately $15 billion annually and growing, and we believe our iFit technology platform is applicable to all major joints in this market. We believe we are the only company offering a broad line of customized knee implants designed to restore the natural shape of a patient's knee. We have sold a total of more than 30,000 knee implants in the United States and Europe. In recent clinical studies, iTotal CR, our cruciate-retaining total knee replacement implant and best-selling product, demonstrated superior clinical outcomes, including better function and greater patient satisfaction compared to traditional, off-the-shelf implants. We recently initiated the limited launch of iTotal PS, our posterior-stabilized total knee replacement implant which addresses the largest segment of the knee replacement market. We expect to submit an application for clearance of iTotal Hip, our first customized hip replacement implant, with the U.S. Food and Drug Administration, or FDA, in 2015.

Our iFit technology platform comprises three key elements:

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

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

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

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

We own or exclusively in-license a total of approximately 470 issued patents and pending patent applications that cover customized implants and patient-specific instrumentation, or PSI, for all major joints and other elements of our iFit technology platform. Our intellectual property portfolio includes 112 issued United States patents, 51 patents issued in countries outside the United States, and 309 patent applications worldwide. We believe that our patent portfolio provides a significant barrier to entry.

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All of our knee replacement products have been cleared by the FDA under the premarket notification process of Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, and have received certification to CE Mark. We market our products to orthopedic surgeons, hospitals and other medical facilities and patients. We have 87 employees engaged in the sales and marketing of our products in the United States, Germany and the United Kingdom. We use independent sales representatives and distributors to complement our own sales and marketing efforts in these and other markets.

We were incorporated in Delaware and commenced operations in 2004. We introduced our iUni and iDuo partial knee replacement products in 2007 and our iTotal CR in 2011. For the year ended December 31, 2014 we generated revenue of $48.2 million from product sales, representing a 39% increase over the prior year. For the three months ended March 31, 2015 we generated revenue of $14.7 million from product sales, representing a 36% increase over the three months ended March 31, 2014.

Financial update

We expect our gross margin to decline for the three months ended June 30, 2015 as compared to the three months ended March 31, 2015, primarily as the result of our hiring of additional manufacturing personnel in advance of production volume increases and increased overtime pay. We believe we will be able to reduce these effects on our gross margins in subsequent periods as production volume increases and we maintain better balance of production employee hiring and work schedules with production needs. Another factor that we expect will contribute to the anticipated gross margin decrease for the three months ended June 30, 2015, as compared to the three months ended March 31, 2015, is increased labor costs associated with the fulfillment of orders for our iTotal PS knee implants, which are in limited launch and are more labor-intensive than our other products with respect to the process of converting CT scans to patient-specific implants. We believe we will be able to reduce the labor costs associated with production of our iTotal PS knee implants when we complete the development of, and receive 510(k) clearance to use, our improved design software. We expect we will complete the development of this software and submit it for 510(k) clearance in the fourth quarter of 2015 and that these labor costs will continue to affect our gross margin until the improved design software is implemented.

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

Revenue from sales of our products fluctuates principally based on the selling price of the joint replacement product, as the sales price of our products varies among hospitals and other medical facilities. In addition, our revenue may fluctuate based on the product sales mix and mix of sales by geography. Our 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 revenue to fluctuate from quarter-to-quarter

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due to a variety of factors, including seasonality, as we have historically experienced lower sales in the summer months and around year-end, the timing of the introduction of our new products, if any, and the impact of the buying patterns and implant volumes of medical facilities.

In April 2015, we entered into a fully paid up, worldwide license agreement with Wright Medical Group, Inc., or Wright Group, and its wholly owned subsidiary Wright Medical Technology, Inc., or Wright Technology and collectively with Wright Group, Wright Medical. Under the terms of this license agreement, we granted a perpetual, irrevocable, non-exclusive license to Wright Medical to use patient specific instrument technology covered by our patents and patent applications with off-the-shelf implants in the foot and ankle. This license does not extend to patient-specific implants. This license agreement provided for a single lump-sum payment by Wright Medical to us of mid-single digit millions of dollars upon entering into the license agreement, which has been paid. This license agreement will expire upon the expiration of the last to expire of our patents and patent applications licensed to Wright Medical, which currently is expected to occur in 2030.

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. This license agreement also provided for a single lump-sum payment by MicroPort to us of low-single digit millions of dollars upon entering into the license agreement, which has been paid. This license agreement will expire upon the expiration of the last to expire of our patents and patent applications licensed to MicroPort, which currently is expected to occur in 2029. We cannot be certain as to the timing or amount of payment of any royalties under this license agreement. We do not at this time anticipate that any such royalties that may be paid to us pursuant to this license agreement will be material in amount, including relative to our revenues.

We do not believe that a termination of either the license agreement with MicroPort or the license agreement with Wright Medical would have a material impact on our business, including on our revenues or results of operations.

Cost of revenue

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

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

Other than as discussed above, we expect our gross margin to expand over time to the extent we are successful in reducing our manufacturing costs per unit and increasing our manufacturing

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efficiency as sales volume increases. We believe that areas of opportunity to expand our gross margins in the future, if and as the volume of our product sales increases, include the following:

- absorbing overhead costs across a larger volume of product sales;
- obtaining more favorable pricing for the materials used in the manufacture of our products;
- increasing the proportion of certain components of our products that we manufacture in-house, which we believe we can manufacture at a lower unit cost than vendors we currently use;
- applying our 3D printing technology to select metal components of our products, which we believe can lower our unit costs compared to our current manufacturing methods;
- developing new versions of our software used in the design of our customized joint replacement implants, which we believe will reduce costs associated with the design process; and
- obtain more favorable pricing of certain components of our products manufactured for us by third parties.

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

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.

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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, as well as in connection with the move of our primary manufacturing facility from Bedford to Wilmington in 2015. We anticipate increased expenses associated with being a public company will include increases in audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs. As our revenue increases we also will incur additional expenses for freight and medical device tax. Our general and administrative expense may fluctuate from period to period due to the timing and extent of the expenses.

Other income (expense), net

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

Income tax provision

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

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Consolidated results of operations

Comparison of the three months ended March 31, 2014 and 2015

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

	2014		2015		2014 vs 2015	
Three months ended March 31,	**Amount**	**As a % of Total Revenue**	**Amount**	**As a % of Total Revenue**	**$ Change**	**% Change**
Revenue	$ 10,799	100%	$ 14,700	100%	$ 3,901	36%
Cost of revenue	7,512	70	9,388	64	1,876	25
Gross profit	3,287	30	5,312	36	2,025	62
Operating expenses:						
Sales and marketing	8,379	78	9,579	65	1,200	14
Research and development	3,578	33	4,016	27	438	12
General and administrative	3,948	37	5,780	39	1,832	46
Total operating expenses	15,905	147	19,375	132	3,470	22
Loss from operations	(12,618)	(117)	(14,063)	(96)	(1,445)	(11)
Total other expenses	(27)	0	(184)	(1)	(157)	(581)
Loss before income taxes	(12,645)	(117)	(14,247)	(97)	(1,602)	(13)
Income tax provision	8	0	10	0	2	25
Net loss	$ (12,653)	(117)	$ (14,257)	(97)	$ (1,604)	(13)

Revenue. Revenue was $14.7 million for the three months ended March 31, 2015 compared to $10.8 million for the three months ended March 31, 2014, an increase of $3.9 million, or 36%, due principally to increased sales of our first primary total knee product, iTotal CR, within the United States as well as increased sales of our other products generally within the United States.

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):

	2014		2015		2014 vs 2015	
Three months ended March 31,	**Amount**	**As a % of Product Revenue**	**Amount**	**As a % of Product Revenue**	**$ Change**	**% Change**
United States	$ 6,952	64%	$ 10,313	70%	$ 3,361	48%
Rest of world	3,847	36	4,387	30	540	14
Product revenue	$ 10,799	100	$ 14,700	100	$ 3,901	36

Revenue in the United States is generated through our direct sales force and independent sales representatives. Revenue outside the United States is generated through our direct sales force and distributors. The percentage of total revenue generated in the United States increased from 64% for the three months ended March 31, 2014 to 70% for the three months ended March 31, 2015. We believe the lower level of US revenue as a percentage of product revenue in the three months ended March 31, 2014 was due to the acceleration of surgical cases in 2013 in anticipation of the implementation of the PPACA.

Cost of revenue, gross profit and gross margin. Cost of revenue was $9.4 million for the three months ended March 31, 2015 compared to $7.5 million for the three months ended March 31, 2014, an increase of $1.9 million or 25%. The increase was due primarily to an increase in production and personnel costs associated with the increase in sales volume. Gross profit increased $2.0 million, or 62%, to $5.3 million, for the three months ended March 31, 2015 as

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compared to $3.3 million for the three months ended March 31, 2014 due to higher sales volume, while our gross margin increased 6 percentage points to 36% from 30%. This increase in gross margin was driven primarily by additional volume related material discounts and better absorption of manufacturing overhead.

Sales and marketing. Sales and marketing expense was $9.6 million for the three months ended March 31, 2015 compared to $8.4 million for the three months ended March 31, 2014, an increase of $1.2 million or 14%. The increase was due primarily to a $1.1 million increase in personnel costs as a result of our hiring of additional direct sales representatives and increases in commissions as a result of the increase in sales volume, and a $0.1 million increase in marketing and other expenses. Sales and marketing expense decreased as a percentage of total revenue to 65% for the three months ended March 31, 2015 from 78% for the three months ended March 31, 2014.

Research and development. Research and development expense was $4.0 million for the three months ended March 31, 2015 compared to $3.6 million for the three months ended March 31, 2014, an increase of $0.4 million or 12%. The increase was due primarily to a $0.4 million increase in personnel costs and a $0.2 million increase in revenue share expenses, offset in part by a $0.3 million decrease in costs for consultants, testing and prototype development. Research and development expenses decreased as a percentage of total revenue to 27% for the three months ended March 31, 2015 from 33% for the three months ended March 31, 2014.

General and administrative. General and administrative expense was $5.8 million for the three months ended March 31, 2015 compared to $3.9 million for the three months ended March 31, 2014, an increase of $1.8 million or 46%. The increase was due primarily to a $0.7 million increase in personnel costs, a $0.7 million increase in freight expense, a $0.4 million increase in consulting services and a $0.4 million increase in various other expenses, offset in part by a decrease of $0.4 million in general and patent legal fees. General and administrative expenses increased as a percentage of total revenue to 39% for the three months ended March 31, 2015 from 37% for the three months ended March 31, 2014.

Other expense, net. Other expense, net was $184,000 for the three months ended March 31, 2015 compared to $27,000 for the three months ended March 31, 2014, an increase of $157,000, or 581%. The increase was primarily due to an increase in interest expense associated with our long-term debt of $10.3 million.

Income taxes. Income tax provision was $10,000 for the three months ended March 31, 2015 compared to $8,000 for the three months ended March 31, 2014. We continue to generate losses for U.S. federal and state tax purposes and have net operating loss carryforwards creating a deferred tax asset. We maintain a full valuation allowance for deferred tax assets.

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Comparison of the years ended December 31, 2013 and 2014

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

	2013		2014		2013 vs 2014	
Year ended December 31,	**Amount**	**As a % of Total Revenue**	**Amount**	**As a % of Total Revenue**	**$ Change**	**% Change**
Revenue	$ 34,597	100%	$ 48,186	100%	$ 13,589	39%
Cost of revenue	27,283	79	30,638	64	3,355	12
Gross profit	7,314	21	17,548	36	10,234	140
Operating expenses:						
Sales and marketing	26,149	76	31,103	65	4,954	19
Research and development	13,779	40	15,107	31	1,328	10
General and administrative	14,693	42	16,763	35	2,070	14
Total operating expenses	54,621	158	62,973	131	8,352	15
Loss from operations	(47,307)	(137)	(45,425)	(94)	1,882	4
Total other expenses	(553)	(2)	(256)	(1)	297	54
Loss before income taxes	(47,860)	(139)	(45,681)	(95)	2,179	5
Income tax provision	29	0	41	0	12	41
Net loss	$ (47,889)	(139)	$ (45,722)	(95)	$ 2,167	5

Revenue. Revenue was $48.2 million for the year ended December 31, 2014 compared to $34.6 million for the prior year, an increase of $13.6 million, or 39%, due principally to increased sales of our first primary total knee product, iTotal CR, and increased sales of our products generally outside the United States.

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):

	2013		2014		2013 vs 2014	
Year ended December 31,	**Amount**	**As a % of Product Revenue**	**Amount**	**As a % of Product Revenue**	**$ Change**	**% Change**
United States	$ 24,681	71%	$ 34,332	71%	$ 9,651	39%
Rest of world	9,916	29	13,854	29	3,938	40
Product revenue	$ 34,597	100	$ 48,186	100	$ 13,589	39

Revenue in the United States is generated through our direct sales force and independent sales representatives. Revenue outside of the United States is generated through our direct sales force and distributors. The revenue allocation or geographic split between United States and rest of world has remained relatively consistent over both periods.

Cost of revenue, gross profit and gross margin. Cost of revenue was $30.6 million for the year ended December 31, 2014 compared to $27.3 million for the year ended December 31, 2013, an increase of $3.3 million or 12%. The increase was due primarily to an increase in production costs and manufacturing supplies associated with the increase in sales volume. Gross profit increased $10.2 million, or 140%, to $17.5 million, in 2014 as compared to $7.3 million in 2013 due to higher sales volume, while our gross margin increased 1,500 basis points to 36% from 21% in 2013. This increase in gross margin was driven by additional volume related material discounts and decreased costs of iJigs and tibial components as a result of the increasing vertical integration of

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our manufacturing processes. The additional unit production volume improved our gross margin as a result of better absorption of manufacturing overhead.

Sales and marketing. Sales and marketing expense was $31.1 million for the year ended December 31, 2014 compared to $26.1 million for the year ended December 31, 2013, an increase of $5.0 million or 19%. The increase was due primarily to a $3.9 million increase in personnel costs as a result of our hiring of additional direct sales representatives and increases in commissions as a result of the increase in sales volume, and a $1.1 million increase in marketing and other expenses. Sales and marketing expense decreased as a percentage of total revenue to 65% in 2014 from 76% in 2013.

Research and development. Research and development expense was $15.1 million for the year ended December 31, 2014 compared to $13.8 million for the year ended December 31, 2013, an increase of $1.3 million or 10%. The increase was due primarily to a $0.7 million increase in revenue share expenses and a $0.7 million increase in costs for consultants, testing and prototype development, offset in part by a $0.1 million decrease in various other expenses. Research and development expenses decreased as a percentage of total revenue to 31% in 2014 from 40% in 2013.

General and administrative. General and administrative expense was $16.8 million for the year ended December 31, 2014 compared to $14.7 million for the year ended December 31, 2013, an increase of $2.1 million or 14%. The increase was due primarily to a $0.9 million increase in general and patent legal fees, a $1.0 million increase in personnel costs, and a $0.8 million charge for a settlement and fully paid-up patent license agreement, offset in part by a decrease of $0.6 million in various other expenses. General and administrative expenses decreased as a percentage of total revenue to 35% in 2014 from 42% in 2013.

Other expense, net. Other expense, net was $0.3 million for the year ended December 31, 2014 compared to $0.6 million for the year ended December 31, 2013, a decrease of $0.3 million, or 54%. The decrease was primarily due to a decrease in interest expense associated with our long-term debt of $0.5 million, partially offset by a $0.2 million loss due to the effect of changes in foreign currency exchange rates on foreign operations.

Income taxes. Income tax provision was $41,000 for the year ended December 31, 2014 compared to $29,000 for the year ended December 31, 2013. The change in income tax expense was due primarily to a provision for foreign income taxes. We continue to generate losses for U.S. federal and state tax purposes and have net operating loss carryforwards creating a deferred tax asset. We maintain a full valuation allowance for deferred tax assets.

Liquidity, capital resources and plan of operations

Sources of liquidity and funding requirements

Since our inception in June 2004, we have financed our operations through private placements of preferred stock, bank debt and convertible debt financings, equipment purchase loans and, beginning in 2007, product revenue. 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 March 31, 2015, we had an accumulated deficit of $282.4 million.

Since 2004, we have raised an aggregate of $330 million from the sale of preferred stock and the exercise of preferred stock warrants and common stock warrants and options.

In June 2011, we entered into a $1.4 million secured term loan facility with the Massachusetts Development Financing Agency, referred to as the MDFA facility, to finance equipment purchases, of which $0.76 million was outstanding as of December 31, 2014. We are scheduled to make monthly interest and principal payments for the MDFA facility through July 2017. For further

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information regarding this facility, see " Credit facilities Massachusetts Development Finance Agency" below.

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

In November 2014, we entered into a senior secured $25 million loan and security agreement with Silicon Valley Bank and Oxford Finance, LLC, referred to as the SVB/Oxford Agreement, consisting of a revolving line of credit, or the Revolving Line, of up to $5 million and commitments for two $10 million term loans. In November 2014, in connection with our entry into the SVB/Oxford Agreement, we drew down the first $10 million term loan, referred to as the SVB/Oxford Term Loan A. We are eligible to draw down the second $10 million term loan on or prior to November 7, 2015 upon meeting certain conditions. As of March 31, 2015, we did not have any revolving loans outstanding under the Revolving Line, with $5 million available for borrowing, subject to our meeting certain conditions, based on our borrowing base under the Revolving Line. We believe our need for the availability of the second $10 million term loan and loans under the Revolving Line will be reduced significantly following this offering. For further information regarding this facility, see " Credit facilities SVB/Oxford" below.

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;
- servicing our indebtedness under our existing credit facilities; and
- preparing, filing and prosecuting patent applications, and maintaining and enforcing our intellectual property rights and position.

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

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

At March 31, 2015, we had cash and cash equivalents of $22.9 million and $4.4 million in restricted cash allocated to lease deposits and funding a contractual commitment to expand our business in Asia, which we refer to as our Asia strategy. See "Certain Relationships and Related-Persons Transactions" for a description of our Asia strategy. Based on our current operating plan, we expect that the net proceeds from this offering, together with our existing cash and cash equivalents as of March 31, 2015, funding available under the SVB/Oxford Agreement and anticipated revenue from operations, including from projected sales of our products, will enable us to fund our operating expenses and capital expenditure requirements and pay our debt service as it becomes due for at least the next 24 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, the gross profit we expect to generate from those revenues and the availability of additional funding under the SVB/Oxford Agreement, 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):

	Year ended December 31,				Three months ended March 31,			
	2013	2014	$ Change	% Change	2014	2015	$ Change	% Change
Net cash (used in) provided by:								
Operating activities	$ (46,826)	$ (43,539)	$ 3,287	7%	$ (11,000)	$ (13,657)	$ (2,657)	(24)%
Investing activities	(8,457)	(1,506)	6,951	82	104	(1,359)	(1,463)	(1407)
Financing activities	69,603	29,337	(40,266)	(58)	(1,347)	58	1,405	104
Effect of exchange rate on cash	167	(613)	(780)	(467)	8	(3)	(11)	(138)
Total	$ 14,487	$ (16,321)	$ (30,808)	(213)	$ (12,235)	$ (14,961)	$ (2,726)	(22)

Cash used in operating activities. Net cash used in operating activities was $13.7 million for the three months ended March 31, 2015 and $11.0 million for the three months ended March 31, 2014, primarily reflecting the net losses during the periods of $14.3 million for the three months ended March 31, 2015 and $12.7 million for the three months ended March 31, 2014. The net cash used in operating activities for the three months ended March 31, 2015 was affected by changes in our operating assets and liabilities, including an increase of $2.6 million in accounts payable and accrued liabilities as well as non-cash stock-based compensation and depreciation totaling $1.6 million, which were offset in part by an increase in our outstanding prepaid and other assets of $1.6 million, an increase in our accounts receivable of $0.7 million and an increase in our inventory of $1.3 million. The net cash used in operating activities for the three months ended March 31, 2014 was affected by changes in our operating assets and liabilities, including non-cash stock-based compensation and depreciation totaling $0.9 million, a decrease in our inventory of $0.6 million and an increase in accounts payable and accrued liabilities of $0.5 million, which was offset in part by an increase in accounts receivable of $0.3 million.

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Net cash used in operating activities was $43.5 million for the year ended December 31, 2014 and $46.8 million for the year ended December 31, 2013, primarily reflecting the net losses during the periods of $45.7 million for the year ended December 31, 2014 and $47.9 million for the year ended December 31, 2013. The net cash used in operating activities for the year ended December 31, 2014 was affected by changes in our operating assets and liabilities, including an increase of $2.1 million in accounts payable and accrued liabilities as well as non-cash stock-based compensation and depreciation totaling $4.6 million, which were offset in part by an increase in our outstanding prepaid and other assets of $0.3 million, an increase in our accounts receivable of $2.9 million and an increase in our inventory of $1.1 million. The net cash used in operating activities for the year ended December 31, 2013 was affected by changes in our operating assets and liabilities, including non-cash stock-based compensation and depreciation totaling $4.2 million, which was offset in part by an increase in our accounts receivable of $2.1 million and an increase in our inventory of $1.4 million.

Net cash (used in) provided by investing activities. Net cash used in investing activities was $1.4 million for the three months ended March 31, 2015 and net cash provided by investing activities was $0.1 million for the three months ended March 31, 2014, a decrease of $1.5 million. These amounts primarily reflect less cash used for purchases of property and equipment and a decrease in restricted cash balances. We anticipate that the amount of cash used in investing activities will increase in 2015 as we purchase additional property and equipment to manufacture more components in our own facility.

Net cash used in investing activities was $1.5 million for the year ended December 31, 2014 and $8.5 million for the year ended December 31, 2013, a decrease of $7.0 million. These amounts primarily reflect less cash used for purchases of property and equipment and a decrease in restricted cash balances.

Net cash (used in) provided by financing activities. Net cash provided by financing activities was $58,000 for the three months ended March 31, 2015 and net cash used by financing activities was $1.3 million for the three months ended March 31, 2014, a decrease of $1.4 million. The decrease was due to a $1.1 million decrease in debt payments and a $0.3 million decrease in proceeds from the issuance of common and preferred stock.

Net cash provided by financing activities was $29.3 million for the year ended December 31, 2014 and $69.6 million for the year ended December 31, 2013, a decrease of $40.3 million. The decrease was due to a $52.0 million decrease in proceeds from the issuance of preferred stock, partially offset by $10.0 million in debt financing and a $2.1 million decrease in debt payments between the two periods. We issued 2.8 million shares of Series E-1 preferred stock during the year ended December 31, 2014 and 9.3 million shares of Series E-1 preferred stock during the year ended December 31, 2013.

Credit facilities

SVB/Oxford

On November 7, 2014, or the effective date, we and ImaTx entered into a senior secured $25 million loan and security agreement with Silicon Valley Bank and Oxford Finance, LLC, which we refer to as the SVB/Oxford Agreement, consisting of a revolving line of credit of up to $5 million (subject to availability under the borrowing base and the satisfaction of other funding conditions), or the Revolving Line, and commitments for two $10 million term loans, or the SVB/Oxford Term Loans. At the time we entered into the SVB/Oxford Agreement, we borrowed the first $10 million term loan, or the SVB/Oxford Term Loan A, and issued the lenders warrants to purchase 33,481 shares of our common stock. We are eligible to borrow a second term loan in a principal amount of $10 million, referred to as the SVB/Oxford Term Loan B, on or prior to November 7, 2015 upon

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meeting certain conditions, including our being able to make certain agreed upon representations and warranties to the lenders and a determination by the lenders, in their sole discretion, that there has been no occurrence of any material adverse change, as defined in the SVB/Oxford Agreement, or any material deviation from the annual financial projections provided by us and accepted by the lenders. Under the SVB/Oxford Agreement, we are required to deliver financial projections in a month-to-month format to the lenders on an annual basis and such lenders may, in their discretion, object to or accept such projections. We prepare our financial projections for this purpose in what we believe is a reasonable manner, including by taking into account trends reported by our sales and marketing team, macroeconomic trends and other relevant data. While we cannot be certain we will achieve our financial projections, we believe that we prepare them in a reasonable, good faith manner. At the time of a request to borrow the SVB/Oxford Term Loan B, the lenders may, in their discretion, determine that there has been a material deviation from the most recent financial projections accepted by the lenders, in which case we would not be entitled to borrow the SVB/Oxford Term Loan B. There can be no assurance that we will be able to borrow the additional $10 million term loan. In the event that we borrow the additional $10 million term loan, we will be obligated to issue warrants to purchase an additional 33,481 shares of our common stock to the lenders under the SVB/Oxford Agreement.

Unless earlier terminated by us or accelerated by the lenders, the Revolving Line terminates on November 7, 2019, with all outstanding revolving credit borrowings and associated interest becoming due and payable upon such termination. Our ability to borrow under the Revolving Line is subject to a borrowing base, calculated as 85% (or such lower percent as Silicon Valley Bank may determine in accordance with the SVB/Oxford Agreement) of eligible accounts receivable. Borrowings under the Revolving Line bear interest at a floating per annum rate equal to the prime rate. Interest on the Revolving Line is payable monthly. In addition to interest, we are obligated to pay a $0.25 million fee for the Revolving Line, which is payable in annual increments of $50,000 due on the effective date and each anniversary of the effective date. We amortize this fee ratably over the term of the Revolving Line. Further, we are obligated to pay a termination fee of $0.1 million if we elect to terminate the Revolving Line prior to the first anniversary of the effective date, or $50,000 if we elect to terminate the Revolving Line between the first and third anniversaries of the effective date, provided that no termination fee will be payable if the Revolving Line is replaced with a new facility or an amended and restated facility from Silicon Valley Bank.

Unless earlier prepaid by us or accelerated by the lenders, the SVB/Oxford Term Loans will each mature on November 1, 2019, referred to as the Term Loan Maturity Date. The SVB/Oxford Term Loan A bears interest at a fixed rate of 7.25% per annum, which rate was determined as the prime rate on the original date of funding, plus 4.0%. To the extent we borrow the SVB/Oxford Term Loan B, such term loan will accrue interest at a fixed per annum rate equal to the prime rate on the date of funding, plus 4.0%. Interest on each of the SVB/Oxford Term Loans is payable monthly in arrears. If we achieve a revenue milestone of $76 million, measured on a trailing 12 month basis for the 12 months ending May 31, 2016, and no event of default has occurred, only interest, and no principal, will be payable for the first 36 months following the effective date. If we do not achieve the revenue milestone, only interest, and no principal, will be payable for the first 24 months following the effective date. After the interest only period, we are required to make equal monthly payments of principal and interest, in arrears, for the remaining term until maturity. In addition to interest, we are obligated to make a final payment fee equal to the original principal amount of the applicable SVB/Oxford Term Loan, multiplied by 7%, on the earliest to occur of the Term Loan Maturity Date, the acceleration of any term loan, or the prepayment of a term loan. Further, with respect to any term loan subject to prepayment prior to the Term Loan Maturity Date, whether by mandatory or voluntary prepayment or acceleration, we will be required to make a prepayment fee equal to 3% of principal amount being prepaid, if such prepayment is made on or prior to the first anniversary of the funding date of the applicable term loan, 2% of the principal amount being

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prepaid, if such prepayment is made after the first anniversary but before the second anniversary of the funding date of the applicable term loan, or 1% of the principal amount being prepaid, if such prepayment is made after the second anniversary of the funding date of the applicable term loan.

Our obligations under the SVB/Oxford Agreement are secured by a first-lien security interest over substantially all of our and ImaTx's assets, other than intellectual property, with respect to which we and ImaTx granted a negative pledge. The SVB/Oxford Agreement contains negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions, incurring indebtedness or liens, paying dividends or making investments and certain other business transactions. There are no financial covenants associated with the SVB/Oxford Agreement. Our obligations under the SVB/Oxford Agreement are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition. Also, immediately upon the occurrence and during the continuance of an event of default, all obligations outstanding under the SVB/Oxford Agreement shall accrue interest at a fixed rate equal to the per annum rate that is otherwise applicable thereto plus 5%.

Massachusetts Development Finance Agency

In June 2011, we entered into a $1.4 million term loan facility with the Massachusetts Development Finance Agency, or MDFA, for the purposes of financing equipment purchases. The MDFA facility, which is subordinated to the SVB/Oxford Term Loans and Revolving Line, is secured on a second-lien basis by certain of our tangible assets. At the time we entered into the MDFA facility, we borrowed the first tranche of $0.6 million, with the remaining funds to be borrowed over the following 18 months. To date, we have borrowed a total of $1.4 million of the available commitments under the facility, of which $0.76 million in loans were outstanding as of December 31, 2014 and $0.7 million as of March 31, 2015. Loans under the MDFA facility bear interest at a fixed rate of 6.5% per annum. Interest is payable monthly in arrears. Beginning on January 1, 2013, we began making payments of principal and interest in 66 equal monthly installments. In connection with our entry into the MDFA facility, we issued warrants to MDFA to purchase 16,000 shares of our Series D preferred stock.

Contractual obligations and commitments

The following table summarizes our outstanding contractual obligations as of March 31, 2015 (in thousands).

	Payment Due by Period				
Contractual Obligations	**Total**	**Less than 1 year**	**Years 2 to 3**	**Years 4 to 5**	**After 5 years**
Senior Secured debt(1)	$ 10,692	$ 211	$ 3,844	$ 6,637	$
Operating lease obligations real estate(2)	5,274	1,629	2,117	744	784
Interest payments on long-term debt(3)	3,121	762	1,283	1,076	
Other(4)	2,005	362	1,304	179	160
Total(5)	$ 21,092	$ 2,964	$ 8,548	$ 8,636	$ 944

(1) Represents amounts payable under the SVB/Oxford Agreement and MDFA facility, assuming that we do not satisfy the $76 million revenue milestone under the SVB/Oxford Agreement, thereby triggering repayment of principal under the facility beginning 24 months after the funding date of the SVB/Oxford Term Loan A in November 2016. See " Liquidity, capital resources and plan of operations Credit facilities" for further detail regarding the milestone.

(2) Represents operating lease commitments for office and manufacturing space in Bedford, Burlington and Wilmington, Massachusetts.

(3) Represents expected interest payments on senior secured debt.

(4) Represents amounts payable under our product royalty agreements, operating leases for office equipment and contracts for marketing exhibit services and a software development collaboration project.

(5) This table does not include: (a) revenue share obligations to past and present members of our scientific advisory board and our Chief Executive Officer, as the amounts of such payments are not known with certainty; and (b) contracts that are entered into in the ordinary course of business that are not material in the aggregate in any period presented above. See " Revenue share agreements" and "Certain Relationships and Related-Persons Transactions Revenue share agreement with Dr. Lang" for a description of our revenue share arrangements.

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Revenue share agreements

We are party to revenue share agreements with certain past and present members of our scientific advisory board under which these advisors agreed to participate on our scientific advisory board and to assist with the development of our customized implant products and related intellectual property. These agreements provide that we will pay the advisor a specified percentage of our net revenue, ranging from 0.2% to 1.33%, with respect to our products on which the advisor made a technical contribution or, in some cases, which we covered by a claim of one of our 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 us on such product sales. Our 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 our patents or patents for which the advisor is a named inventor that claims the applicable product.

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

The aggregate revenue share percentage of net revenue from our currently marketed knee replacement products, including percentages under all of our scientific advisory board and Chief Executive Officer revenue share agreements, ranges, depending on the particular product, from 3.4% to 5.8%. We incurred aggregate revenue share expense, including all amounts payable under our scientific advisory board and Chief Executive Officer revenue share agreements, of $1.4 million during the year ended December 31, 2013, representing 4.0% of revenue, $2.3 million during the year ended December 31, 2014, representing 4.8% of revenue, $0.6 million during the three months ended March 31, 2014, and $0.8 million during the three months ended March 31, 2015. See "Certain Relationships and Related-Persons Transactions Revenue share agreement with Dr. Lang" for further information regarding our arrangement with our Chief Executive Officer.

Off-balance sheet arrangements

Through March 31, 2015, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical accounting policies and significant judgments and use of estimates

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which had been prepared in conformity with accounting principles generally accepted in the United States that require us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting periods. The accounting estimates that require our

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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.

Revenue

We generate 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.

We recognize revenue when all of the following criteria are met:

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

For a majority of sales to medical facilities, we recognize 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, we recognize 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 we do not offer rights of return or price protection and we have no post-delivery obligations.

Accounts receivable and allowance for doubtful accounts

The majority of our accounts receivable balances consist of amounts due from medical facilities. In estimating whether accounts receivable can be collected, we perform evaluations of customers and continuously monitor collections and payments and estimate an allowance for doubtful accounts based on the aging of the underlying invoices, 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. We also review our inventory value to determine if it reflects 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.

Intangibles and other long-lived assets

Intangible assets consist of developed technology and other intellectual property rights in-licensed from ImaTx as part of the spin-out transaction in 2004. Intangible assets are carried at cost less accumulated amortization. We test impairment of long-lived assets when events or changes in circumstances indicate that the assets might be impaired. For assets with determinable

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useful lives, amortization is computed using the straight-line method over the estimated economic lives of the respective intangible assets.

Furthermore, periodically we assess 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, we may be required to record impairment charges. During 2013 and 2014 and for the three months ended March 31, 2015, no such impairment charges were recognized.

Medical device excise tax

We are subject to the Health Care and Education Reconciliation Act of 2010, 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. We incurred medical device excise tax expense of $0.4 million for the year ended December 31, 2013, $0.7 million for the year ended December 31, 2014, $0.1 million for the three months ended March 31, 2014 and $0.2 million for the three months ended March 31, 2015, which amounts are included in general and administrative expense.

Share-based compensation and common stock valuation

Stock-based compensation

We measure the cost of awards of equity instruments based on the grant date fair value of the awards. We use the Black-Scholes option pricing model to determine the weighted-average fair value of options granted and recognize the compensation expense of stock-based awards on a straight-line basis over the vesting period of the award.

The fair value of stock-based payment awards using 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. Our estimates of these important assumptions are primarily based on third-party valuations, historical data, peer company data and our judgment regarding future trends and other factors.

The fair value of options at date of grant was estimated using the Black-Scholes option pricing model. The following assumptions were used for the options that were granted in the respective periods, if any:

	Years Ended December 31,		Three Months Ended March 31,	
	2013	2014	2014	2015
			(unaudited)	
Risk-free interest rate	0.78% - 1.61%	1.66% - 2.29%		1.37% - 1.67%
Expected term (in years)	5.00 - 6.25	5.00 - 7.25		5.47 - 6.45
Dividend yield	0.00%	0.00%		0.00%
Expected volatility	55.00%	50.00%		50.00%

We recognized employee stock-based compensation expense of $2.3 million for the year ended December 31, 2013, $2.6 million for the year ended December 31, 2014, $0.5 million for the three months ended March 31, 2014 and $1.1 million for the three months ended March 31, 2015, which amounts were calculated based on awards ultimately expected to vest based on historical

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forfeiture rates to date, the amount of stock-based compensation capitalized as part of inventory was not material.

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

	Years Ended December 31,		Three Months Ended March 31,	
	2013	2014	2014	2015
			(unaudited)	(unaudited)
Cost of revenues	$ 179	$ 162	$ 41	$ 110
Sales and marketing	439	597	113	210
Research and development	879	628	98	254
General and administrative	840	1,163	213	514
	$ 2,337	$ 2,550	$ 465	$ 1,088

At March 31, 2015, we had $5.8 million of total unrecognized compensation expense that will be recognized over a weighted-average period of 2.56 years.

Common stock valuations

The fair value of the shares of our common stock underlying our stock options has historically been determined by our board of directors. Because there has been no public market for our common stock and in the absence of recent arm's-length cash sales transactions of our common stock with independent third parties, our board of directors has determined the fair value of our common stock by considering at the time of grant a number of objective and subjective factors. Our board of directors intends all options granted to be exercisable at a price per share not less than the per share fair value of our common stock underlying those options on the date of grant. The estimated fair value of our common stock was determined at each valuation date in accordance with the guidelines outlined in the American Institute of Certified Public Accountants, or AICPA, Audit and Accounting Practice Aid, "Valuation of Privately Held Company Equity Securities Issued as Compensation". Our board of directors, with the assistance of management, developed these valuations using significant judgment and taking into account numerous factors, including the following:

- independent third-party valuations as of November 30, 2012, September 30, 2013, January 31, 2014, May 31, 2014, November 30, 2014 and March 31, 2015;
- progress of research and development activities, including receipt of regulatory clearances and product launches;
- our operating and financial performance, including our revenues, gross margins and levels of available capital resources;
- rights and preferences of our common stock compared to the rights and preferences of our other outstanding equity securities;
- equity market conditions affecting comparable public companies, as reflected in comparable companies' market multiples, IPO valuations and other metrics;
- the likelihood of achieving a liquidity event for the shares of common stock, such as an IPO given prevailing market and medical device sector conditions;

sales of our convertible preferred stock in arms-length transactions;

the illiquidity of our securities by virtue of being a private company;

business risks; and

management and board experience.

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We considered the following approaches in the preparation of our valuations:

Income approach. The income approach is based on the premise that the value of a business is the present value of the future earning capacity that is available for distribution to investors. It involves estimating the discounted cash flow, or DCF, for the business by projecting the free cash flows each year, calculating a terminal value, and then discounting these cash flows back to a present value at an appropriate discount rate that takes into account the time value of money and the risk inherent in the business.

Market approach. The market approach values a business by reference to guideline companies for which enterprise values are known. This approach has two principal methodologies. The guideline public company methodology derives valuation multiples from the operating data and share prices of similar publicly traded companies. The guideline acquisition methodology focuses on comparisons between the subject company and guideline acquired public or private companies.

Asset approach. The asset approach is based on the premise that the value of a business is the cost of replacing all of the assets of that business, both tangible and intangible. It involves estimating the cost of reproducing or replacing all property in the business, less depreciation for physical deterioration and functional obsolescence.

Option-pricing method backsolve, or OPM backsolve. The OPM backsolve method derives the implied equity value for a company from a recent transaction involving the company's own securities issued on an arms-length basis.

Probability weighted expected return method. Using the probability weighted expected return method, or PWERM, the value of a company's common stock is estimated based upon the analysis of future values for the company assuming various possible future liquidity events such as an initial public offering, or IPO, sale or merger. Share value is based upon the probability-weighted present value of expected future net cash flows, considering each of the possible future events, as well as the rights and preferences of each share class.

In addition, we also considered an enterprise value allocation method:

Option-pricing method, or OPM. Under this method, each class of stock is modeled as a call option with a distinct claim on the enterprise value of the company. The options' exercise prices would be based on a comparison with the enterprise value. The method assumes that a formula, such as the Black-Scholes option pricing model, would calculate the fair value when provided with certain values, including share price, expiration date, volatility and the risk free interest rate.

For the valuations performed as of September 30, 2013 and January 31, 2014, we estimated the per share common stock value by allocating the enterprise value of the company using a hybrid allocation method that utilized a combination of the OPM method and a scenario analysis that may be considered to be part of a PWERM. We determined the common stock value was $7.32 as of September 30, 2013 and $8.12 as of January 31, 2014. For the valuations performed as of May 31, 2014, November 30, 2014 and March 31, 2015, we estimated the per share common stock value by allocating our enterprise value using the PWERM method. We determined the common stock value was $8.96 as of May 31, 2014, $10.18 as of November 30, 2014 and $15.26 as of March 31, 2015.

In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the expected time to liquidity. The estimated fair value of our common stock at each

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grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

The key subjective factors and assumptions used in our valuations primarily consisted of:

- the selection of the appropriate market comparable transactions;
- the selection of the appropriate comparable publicly traded companies;
- the financial forecasts utilized to determine future cash balances and necessary capital requirements;
- the probability and timing of the various possible liquidity events;
- the estimated weighted-average cost of capital; and
- the discount for lack of marketability of our common stock.

The following table sets forth information about our stock option grants since January 1, 2013 on each date on which we granted stock options:

Grant Date	Number of Options Granted	Exercise Price $	Estimated fair value of common stock per share used to determine stock-based compensation expense $
4/2/2013	483,155	5.5	3.54
6/11/2013	386,385	5.5	3.54
8/4/2014	616,050	8.96	8.96
8/4/2014	413,050	10.96	8.96
9/17/2014	7,500	10.96	8.96
1/13/2015	334,336	10.96	10.18
2/5/2015	12,500	10.96	10.18
4/28/2015	20,000	15.26	15.26
	2,273,923		

At each grant date the board of directors reviewed any recent events and their potential impact on the estimated fair value per share of the common stock. For grants of stock awards made on dates for which there was no valuation performed by an independent third party, our board of directors considered the most recent independent third-party valuation and other pertinent information available to it at the time of grant. As provided for in Code Section 409A, we generally rely on independent third-party valuations for up to 12 months unless we experienced a material event that would have affected the estimated fair value per common share.

Following the closing of this offering, the fair value of our common stock will be determined based on the closing price of our common stock on the grant date.

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.

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Interest rate risk

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

Foreign currency exchange risk

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies could adversely affect our financial results. Approximately 29% of our revenue from product sales for the years ended December 31, 2013 and 2014, 30% for the three months ended March 31, 2015 and 36% for the three months ended March 31, 2014 were denominated in foreign currencies, and 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 $0.3 million for the year ended December 31, 2013 and $0.5 million for the year ended December 31, 2014. A 10% increase or decrease in foreign currency exchange rates would not have had a material impact on our consolidated financial statements for the three months ended March 31, 2014 or for the three months ended March 31, 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.

Segment information

We have one primary business activity and operate as one reportable segment.

JOBS Act accounting election

The Jumpstart our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

Recent accounting pronouncements

In August 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40) Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (ASU 2014-15). This ASU provides guidance about management's responsibility to evaluate whether there is a substantial doubt about an entity's ability to continue as a going

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concern and to provide related footnote disclosures. Specifically, this ASU defines the term substantial doubt, requires an evaluation of every reporting period including interim periods, provides principles for considering the mitigating effect of management's plan, requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, requires an express statement and other disclosures when substantial doubt is not alleviated, and requires an assessment for a period of one year after the date that the financial statements are issued or available to be issued. ASU 2014-15 is effective for annual periods beginning after December 15, 2016 and interim periods within those reporting periods. Earlier adoption is permitted. We are currently evaluating the impact of this pronouncement on our consolidated financial statements.

In April 2014, FASB issued ASU No. 2014-08, Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity. This ASU amendment changes the requirements for reporting discontinued operations in Subtopic 205-20. The amendment is effective on a prospective basis for financial statements issued for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2014. Early adoption is permitted for disposals that have not been reported in financial statements previously issued. We will apply the provisions of this ASU to any future transactions that qualify for reporting discontinued operations.

In May 2014, FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. This ASU's effective date will be the first quarter of fiscal year 2017 using one of two retrospective application methods. We have not determined the potential effects of this ASU on our consolidated financial statements.

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BUSINESS

Overview

We are a medical technology company that uses our proprietary iFit Image-to-Implant technology platform to develop, manufacture and sell joint replacement implants that are individually sized and shaped, which we refer to as customized, to fit each patient's unique anatomy. The worldwide market for joint replacement products is approximately $15 billion annually and growing, and we believe our iFit technology platform is applicable to all major joints in this market. We believe we are the only company offering a broad line of customized knee implants designed to restore the natural shape of a patient's knee. We have sold a total of more than 30,000 knee implants in the United States and Europe. In recent clinical studies, iTotal CR, our cruciate-retaining total knee replacement implant and best-selling product, demonstrated superior clinical outcomes, including better function and greater patient satisfaction compared to off-the-shelf implants. We recently initiated the limited launch of iTotal PS, our posterior-stabilized total knee replacement implant which addresses the largest segment of the knee replacement market. We expect to submit an application for clearance of iTotal Hip, our first customized hip replacement implant, with the U.S. Food and Drug Administration, or FDA, in 2015.

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 a computed tomography, or CT, scan of the patient and to prepare a surgical plan customized for the patient that we call iView.

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

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

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

Manufacturers of traditional knee replacement implants offer products with a limited range of sizes and geometries, which we refer to as off-the-shelf implants. Off-the-shelf implants are not designed to restore a particular patient's unique anatomy. Our summary of one study indicates that approximately one in five patients who receives an off-the-shelf total knee replacement is not satisfied with the results. See " Industry Background Knee implants" for a description of our summary of this study.

Based on clinical data developed independently by orthopedic surgeons comparing our iTotal CR to off-the-shelf total knee replacement implants, as well as our own research and the common approach we employ in the design and manufacture of our products, we believe that our customized knee replacement implants offer significant benefits to the patient, the surgeon and the hospital that are not afforded by off-the-shelf implants.

For the patient. We believe that our individualized approach offers better clinical outcomes when compared to off-the-shelf implants based on the following measures:

Better fit. We design our customized knee implants to restore the patient's own native anatomy. As a result, we believe that our implants fit better.

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Faster recovery. We believe an individual fit requires less bone and soft tissue removal by the surgeon, thereby shortening recovery times.

Better function. We design our customized knee implants to follow the particular shape and contour of the patient's knee. As a result, we believe our implants offer an increased potential for a knee that moves more naturally and is more stable.

Greater patient satisfaction. We believe our implants offer patients greater overall satisfaction with the results of their knee replacement.

For the surgeon. We believe that the combination of the use of our iJigs with our customized knee replacement implants enables a more accurate, reproducible and simplified surgical procedure by reducing the number of required steps and increasing the precision of the placement of the implant. Our summary of a retrospective study of 200 knee replacement surgeries published in 2014 in the peer-reviewed *Journal of Arthroplasty*, or the 2014 JOA Study indicates that our iTotal CR implant was 1.8 times more likely to be in the desired alignment range after surgery than an off-the-shelf implant. One of the authors of this study is a paid consultant to us.

For the hospital. We believe that our customized knee replacement implants and iFit technology platform provide a better economic outcome for hospitals by:

improving patient recovery times, reducing blood loss and reducing adverse event rates at discharge;

reducing the costs associated with managing and sterilizing large numbers of reusable instruments; and

improving turnaround times with the potential for more procedures to be completed within the same amount of time and for the hospital to generate additional revenue.

We own or exclusively in-license a total of approximately 470 issued patents and pending patent applications that cover customized implants and patient-specific instrumentation, or PSI, for all major joints and other elements of our iFit technology platform. Our intellectual property portfolio includes 112 issued United States patents, 51 patents issued in countries outside the United States, and 309 patent applications worldwide. We believe that our patent portfolio provides a significant barrier to entry.

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, hospital networks, ambulatory surgery centers and other medical facilities, and patients. We have 87 employees engaged in the sales and marketing of our products in the United States, Germany and the United Kingdom. We use independent sales representatives and distributors to complement our own sales and marketing efforts in these and other markets.

We introduced our iUni and iDuo partial knee replacement products in 2007 and our iTotal CR in 2011. For the year ended December 31, 2014, we generated revenue of $48.2 million from product sales, representing a 39% increase over the prior year. For the three months ended March 31, 2015, we generated revenue of $14.7 million from product sales, representing a 36% increase over the three months ended March 31, 2014.

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Industry background

Market opportunity

Joint replacement for treatment of osteoarthritis

Osteoarthritis is the principal condition that leads to joint replacement surgery. Osteoarthritis is a degenerative joint disease characterized by the breakdown of the cartilage that protects and cushions key joints in the body, including the knees, hips and shoulders. This causes the bones in the affected joint to rub against each other, which can result in significant and chronic joint pain, stiffness, swelling, numbness, loss of flexibility and loss of motor function. The pain of osteoarthritis, even during the early stages of the disease, can be overwhelming for patients and can have significant physical, psychological, quality of life and financial implications.

An estimated 27 million people in the United States and 630 million people worldwide suffer from osteoarthritis. Compelling demographic trends, such as the growing population of aging yet active individuals and rising rates of obesity, are expected to be key drivers in the continued growth of osteoarthritis occurrence. The National Institutes of Health, or NIH, projects that by 2030, approximately 70 million people in the United States will be 65 years or older and will be at high risk of developing osteoarthritis. Osteoarthritis is more common in adults over the age of 50, but the condition and precursors of the condition can be observed much earlier.

For moderate to advanced cases of osteoarthritis, a surgical procedure may be required to replace the damaged joint. During this joint replacement, or arthroplasty, procedure, a surgeon removes the damaged bone in the affected joint and inserts an implant as a replacement. The joint implant may replace all of the principal components of the joint, in which case the procedure is referred to as a total joint replacement, or may replace only a portion of the joint, in which case the procedure is referred to as a partial joint replacement. According to data from the American Academy of Orthopaedic Surgeons, or AAOS, most patients who undergo primary total knee arthroplasty, or TKA, and primary total hip arthroplasty, or THA, are aged 50 to 80 years old. However, our summary of presentations made at the 2014 annual meeting of the AAOS indicates that increased use of these procedures in patients between 45 and 64 years old has fueled recent growth in the TKA and THA markets. Based on these trends, we expect patient demand for total joint replacements will continue to increase.

Joint replacement market

According to the Orthopaedic Industry Annual Report published in March 2015 by Orthoworld Inc., or the 2014 Orthoworld Report, worldwide sales of joint replacement products, including replacements for knees, hips, shoulders, elbows, wrists, ankles and digits outside of trauma, exceeded $15.4 billion in 2014 and are expected to grow to approximately $18 billion by the end of 2020. The 2014 Orthoworld Report estimated that worldwide sales of knee replacement products totaled approximately $7.5 billion in 2014. According to the Orthopaedic Industry Annual Report published in May 2014 by Orthoworld Inc., or the 2013 Orthoworld Report, 2013 estimated sales of knee replacement products in the United States represented approximately 56% of total estimated worldwide sales of such products.

According to the industry report U.S. Market for Large Bone and Joint Orthopedic Devices published in February 2014 by iData Research, or the iData Report, primary total knee replacement implants and partial knee replacement implants accounted for approximately 83% of the 2013 knee replacement market by revenue in the United States. The remaining 17% of the knee replacement market is for follow up procedures known as revision surgeries and patient-specific instruments. According to the iData Report, in 2013, of the primary total knee replacement market in the United States, posterior-stabilized procedures represented approximately 72% by revenue and cruciate-

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retaining procedures represented approximately 28% by revenue. The decision to perform a posterior-stabilized or cruciate-retaining total knee replacement is usually a matter of a surgeon's preferred surgical technique.

In 2014, according to the 2014 Orthoworld Report, worldwide sales of hip replacement products totaled approximately $6.3 billion. According to the 2013 Orthoworld Report, 2013 estimated sales of hip replacement products in the United States represented approximately 54% of total estimated worldwide sales of such products. According to the iData Report, primary total hip replacement implants accounted for approximately 69% by revenue of the 2013 hip replacement market in the United States.

The market for joint replacements extends beyond knee and hip replacements. For example, the treatment of osteoarthritis in the extremities, including the shoulder, elbow, wrist and digit, may involve the replacement of the affected joint. According to the 2014 Orthoworld Report, the worldwide extremities joint replacement market was estimated at $1.6 billion in 2014.

Knee implants

Knee replacement implants typically have four principal components:

- a metal femoral component that is placed over the end of the femur, which is the bone extending from the hip to the knee;
- a metal tibial component that is placed over the end of the tibia, which is the bone extending from the knee to the ankle;
- a plastic spacer typically made of polyethylene that is attached to the tibial component and is the surface across which the femoral component glides; and
- a plastic button typically made of polyethylene to resurface the knee cap, or patella.

The tibial and femoral components are attached to the patient's bone using acrylic cement. The surfaces where the metal components meet are referred to as articular surfaces.

Clinical shortcomings of off-the-shelf knee implants

Knees vary in size and shape; no two knees are the same. In a traditional knee replacement procedure, the surgeon must choose an off-the-shelf implant with a size and shape that the surgeon thinks will work best for the patient. However, off-the-shelf implants are not customized to fit an individual patient's knee, and during a knee replacement procedure, the surgeon has to fit the patient's soft tissue, bones and cartilage to the fixed dimensions of the implant through an iterative process of sizing and positioning. This typically entails removing bone and shaping the residual bone to the implant. Surgeons often have to make compromises on implant fit, rotation and alignment because the surgeons are limited by the size and shape of the implant. These compromises can cause residual pain and functional limitations after surgery, which we believe contribute to patient dissatisfaction. We reviewed a study of 1,703 patients published in 2009 in the peer-reviewed journal *Clinical Orthopaedics and Related Research* where patient satisfaction was determined by combining patients who answered very dissatisfied, dissatisfied or neutral into one group and patients who answered satisfied or very satisfied into a second group. Our summary of the study indicates that approximately one in five patients who receive an off-the-shelf implant is not satisfied with his or her total knee replacement.

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We believe that the typical compromises surgeons must make with off-the-shelf implants can affect patient outcomes in the following important ways:

Improper implant fit. The femoral or tibial component of an off-the-shelf implant frequently protrudes beyond the edge of the bone, which is referred to as overhang. Overhang of three millimeters or greater is associated with an almost two fold increased risk of pain at two years after total knee replacement. Our summary of a study of 437 total knee replacements performed by a single surgeon with off-the-shelf implants published in 2010 in the peer-reviewed *Journal of Bone and Joint Surgery* indicates that 68% of women and 40% of men had femoral overhang of three millimeters or more. An off-the-shelf implant also may not fully cover the femur or the tibia, referred to as undersizing. Femoral and tibial undersizing may be associated with increased blood loss during surgery and an increased risk of osteolysis, or resorption and loss of bone, which may lead to costly transfusions and tibial implant loosening and failure.

The graphic below depicts femoral overhang, femoral undersizing, tibial overhang and tibial undersizing with an off-the-shelf knee implant:

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Component malrotation. The placement of the femoral or tibial component of an off-the-shelf implant frequently is not aligned, or is malrotated, with the proper rotational axis of the patient's knee. Our summary of a 2010 study published in the peer-reviewed *Journal of Bone and Joint Surgery British* indicates that 56% of painful total knee replacements were found to have significant rotational errors of the femoral and/or tibial components. In addition, our summary of a study of 28 total knee replacements with off-the-shelf implants published in 2001 in *Clinical Orthopaedics and Related Research* indicates that patients with improper component rotation were found to be five times more likely to experience knee pain than a control group of patients.

In order to achieve proper tibial rotation, there are often tradeoffs among proper sizing, coverage and placement with off-the-shelf implants. The graphic below depicts proper rotation and malrotation of the tibial component:

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Unnatural movement and feeling. The femoral component of an off-the-shelf implant has a fixed geometry that typically does not match the patient's natural curvatures, or "J" curves, of the surfaces of the condyles, which are the rounded lobes at the end of the femur. The femoral component of an off-the-shelf implant also does not match the inside, referred to as medial, or outside, referred to as lateral, joint lines. As a result, the implant may force the patient's knee into an unnatural motion that interferes with the normal functioning of the patient's ligaments. This frequently results in abnormal forward sliding of the femur during knee bend and up-and-down rocking, or lift off, of the condyles. Our summary of a study of 253 patients at least one year after total knee replacement with an off-the-shelf implant, published in 2006 in *Clinical Orthopaedics and Related Research* indicates that dissatisfied patients reported that their knee did not feel normal at more than twice the rate of satisfied patients. In addition, our summary of an abstract presented at the 2014 International Congress for Joint Reconstruction Pan-Pacific Orthopedic Congress, or 2014 ICJR Pan-Pacific Congress indicates that five of nine patients with off-the-shelf knee replacements implanted by the same surgeon experienced abnormal lift-off of their femoral condyles during a deep knee bend. We provided financial support for this study. One of the authors of this study also is a paid consultant to us.

The graphic below depicts abnormal femoral lift-off, one of the potential unnatural movements, in a knee replacement with an off-the-shelf implant.

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Other challenges associated with off-the-shelf implants

In addition to the residual pain and functional limitations suffered by patients, we believe procedures using off-the-shelf knee implants present several intra-operative and economic challenges for surgeons and hospitals, including:

For the surgeon. The surgical procedure is complex. Pre-operatively, the surgeon typically compares a two dimensional outline of the implant with the patient's x-ray images. This process provides only a rough estimate of the fit of the implant to the patient. Intra-operatively, the surgeon must perform repetitive and time-consuming cutting of tissue and fitting of trial implants. We believe that in many cases, the surgical procedure with an off-the-shelf knee implant involves more than 10 major steps and more than 100 sub-steps.

For the hospital. We estimate that a total knee replacement procedure using an off-the-shelf implant requires approximately five to 10 costly double-tiered, sterilized instrument trays. Hospitals often store these trays from multiple manufacturers, occupying valuable space. Generally, the implant manufacturer provides these instruments to the hospital free of charge. However, the hospital must pay the cost of cleaning, sterilizing and storing the instruments between each surgical procedure. In addition, if instruments are not properly prepared, they are a potential source of costly infections. Many insurers and third-party payors, including Medicare, require the hospital to bear the costs of infections occurring within 90 days following a surgical procedure.

Recent efforts to improve traditional knee replacement surgery

In an effort to overcome some of the shortcomings associated with off-the-shelf implants, manufacturers have focused on improving traditional knee replacement procedures. We believe, however, that these efforts do not fully address the needs of patients, surgeons and hospitals:

Patient-specific instrumentation, or PSI. Many manufacturers offer patient-specific instrumentation for use with their off-the-shelf implants. While this approach has the potential to reduce the number of trays and the quantity of instruments hospitals must manage, the patient still receives an off-the-shelf implant with the limitations described above.

Robotic assistance. Some manufacturers offer robotic systems for use in planning and executing some types of knee replacement surgeries. These robotic systems are expensive to purchase and maintain. In addition, the patient still receives an off-the-shelf implant with the limitations described above.

Increased range of sizes. Some manufacturers offer a greater range of sizes for their off-the-shelf implants, including gender-specific implants. Generally, however, these implants are limited by a fixed shape and size that do not conform to the unique geometry of each patient. As a result, these implants also are subject to the limitations described above.

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The ConforMIS Solution: One Patient, One Implant

No two joints are the same; accordingly, we believe no two implants should be the same. We believe our customized joint replacement products and proprietary technology create an opportunity to disrupt the large, existing market for off-the-shelf orthopedic implants. Our summary of a survey of 356 orthopedic surgeons conducted by iData Research during the 2014 annual meeting of the American Academy of Orthopaedic Surgeons indicates that approximately 47% of respondents claimed to see a benefit to using custom implants.

We use our proprietary iFit Image-to-Implant technology platform to design and manufacture customized knee implants that are precisely sized and shaped to fit the unique three-dimensional curvatures of each patient's knee, as well as associated customized, single-use patient-specific instrumentation, which we refer to as iJigs. We believe our proprietary iFit technology platform is applicable to all major joints.

iFit Image-to-Implant technology platform

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 iJigs based on a CT scan of the patient and to prepare a surgical plan customized for the patient that we call iView.

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

iFit Just-in-Time Delivery, our just-in-time manufacturing and delivery capabilities. We manufacture the customized replacement joint and iJigs to order and do not maintain significant inventory of finished products. We deliver the customized knee replacement implant and iJigs to the hospital in advance of the scheduled arthroplasty procedure.

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 off-the-shelf implants.

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Our customized implant procedure

The principal steps involved in the application of our iFit technology platform to the delivery of a customized knee implant to the hospital and surgical plan to the surgeon include:

CT scan
The surgeon orders a standard diagnostic CT scan of the patient's knee, along with a few CT images of the hip and ankle. The CT scan is then sent to ConforMIS.

Recreating the knee using three-dimensional modeling
We use our proprietary algorithms and computer software to map the articular surfaces of the knee joint, define the areas of disease and convert the imaging data into a three-dimensional model of the knee. Our software is designed to correct for deformities caused by osteoarthritis and to digitally recreate the biomechanical axes of the patient's knee, which is important in determining proper rotation and alignment of the implant.

Personalizing the implant
Our engineers use computer-aided design, or CAD, software to design the customized implant and iJigs that will precisely match the three-dimensional model of the patient's knee. We are able to model the implant contact surfaces and maximize contact area for each patient with the goal of reducing polyethylene wear, a common reason for implant failure.

Development of patient-specific surgical plan
For each patient, we generate and provide the surgeon with iView, which allows the surgeon to visualize all preoperative planning information, including surgical steps, measurements and orientations. We make iView available to the surgeon electronically in advance of the procedure and include iView in a single package with our customized implant and iJigs.

Just-in-time delivery to hospital
We deliver the patient's customized knee implant and iJigs to the hospital in advance of the surgery. We are able to deliver our iUni, iDuo and iTotal CR products within six to seven weeks of the date of our receipt of an order and the CT scan, and we expect a similar delivery time for our iTotal PS.

Key benefits of our customized products

We use our iFit technology platform to develop customized joint replacement systems and single-use surgical instruments. Based on clinical data developed independently by orthopedic surgeons comparing our iTotal CR to off-the-shelf total knee replacement implants, as well as our own research and the common approach we employ in the design and manufacture of all of our products, we believe that our customized knee replacement implants offer significant benefits to the patient, the surgeon and the hospital that are not afforded by off-the-shelf implants.

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For the patient. We believe that our individualized approach offers better clinical outcomes when compared to off-the-shelf implants based on the following measures:

Better fit. Using our proprietary algorithms and computer software, we design our customized knee implants to restore the patient's own native anatomy, avoid femoral and tibial overhang and undersizing and provide proper tibial component rotation. As a result, we believe that our implants fit better, which is important to minimize pain and maintain the integrity of the implant.

Faster recovery. We believe an individual fit requires less bone and soft tissue removal by the surgeon, resulting in less bleeding and swelling within the knee and shortened recovery times. Our summary of a study of 132 total knee replacements presented at the 2013 Annual Meeting of the British Association for Surgery of the Knee, or the 2013 BASK Study indicates that the use of our iTotal CR resulted in a statistically significant reduction in bone resections ($p<0.001$), thereby preserving more of the patient's bone, and required statistically significantly fewer soft tissue cuts ($p=0.046$) than an off-the-shelf implant. We determine statistical significance based on a widely used, conventional statistical method that establishes the p-value of observed results. Typically, a p-value of 0.05 or less represents statistical significance, meaning that there is less than a one-in-20 likelihood that the observed results occurred by chance. The investigator who conducted this study is a paid consultant to us and a member of our scientific advisory board.

Better function. We design our customized implants to match the patient's natural "J" curves, corrected for deformities caused by osteoarthritis, preserve the patient's medial and lateral joint lines, and minimize up-and-down rocking and lift-off of the patient's condyles during normal knee movement. As a result, we believe that our implants have the potential to offer a more stable, natural feeling knee with normal kinematic pattern and function. Our summary of an abstract presenting ConforMIS-sponsored research at the 2014 ICJR Pan-Pacific Congress indicates that 10 of 11 patients studied with an iTotal CR as compared to only five of nine patients studied with off-the-shelf knee replacements showed a normal motion pattern for the lateral condyle during a deep knee bend. All procedures were performed by the same surgeon. This differential between the two groups was observed despite the apparent success of the implant procedure in all 20 patients based on a commonly used scoring system. We provided financial support for this study. Two of the authors of this study also are paid consultants to us, and one of them is a member of our scientific advisory board.

Greater patient satisfaction. We believe our customized implants offer patients greater overall satisfaction with the results of their knee replacement. Our summary of a retrospective study of 70 patients who had undergone total knee replacement presented at the 2015 International Congress for Joint Reconstruction World Arthroplasty Conference, or the 2015 ICJR Arthroplasty Conference indicates that the self-reported patient satisfaction score was statistically significantly higher in patients who had received our iTotal CR ($p=0.04$) than in a control group of patients who had received an off-the-shelf knee implant.

Earlier intervention. We believe that patients who undergo knee replacement with one of our products typically retain more of their bone during the surgical procedure, as compared to patients who undergo knee replacement using an off-the-shelf implant. The more bone that is preserved, the more likely the patient will have sufficient bone available if a revision surgery is necessary. As a result, patients may undergo knee replacement surgery at an earlier age.

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For the surgeon. We believe that our iFit technology platform offers an improved surgical procedure and greater efficiencies for surgeons when compared to knee replacements with off-the-shelf implants based on the following measures:

Improved surgical procedure. We believe that the combination of the use of our iJigs with our customized knee implants enable a more accurate, reproducible and simplified surgical procedure by reducing the number of steps and increasing the precision of implant alignment. In our procedure, the surgeon makes a predetermined set of cuts that are specifically tailored to each patient and designed to result in a precise fit without the need for repetitive cutting of tissue and fitting of trial implants associated with an off-the-shelf knee replacement. Our summary of the 2014 JOA Study indicates that our iTotal CR implants were 1.8 times more likely to be in the desired alignment range after surgery than an off-the-shelf implant.

Bone preservation. We believe our knee implants result in the preservation of more bone for several reasons:

We use our iFit technology platform to design each of the bone cuts required to fit our customized implants so as to minimize bone resection and maximize bone preservation for the individual patient.

Our femoral component is fitted using six cuts of the femur as compared to the five cuts typically used with off-the-shelf implants. We reviewed an abstract presented at the 2012 Annual Meeting of the British Association for Surgery of the Knee, which studied stress and fatigue in a six-cut femoral implant model that was thinner than a five-cut model by an average of two millimeters. The six-cut implant model displayed substantially lower maximum stress than a five-cut model at a known high-stress location. Two of the authors of this study are our employees, and two of the authors of this study are paid consultants to us. Based in part on this data, we believe our six-cut implants can be thinner than off-the-shelf implants without sacrificing implant strength. We believe a thinner implant requires the surgeon to remove less bone during implantation.

Our summary of the 2013 BASK Study indicates that the average total of all bone resection measurements for total knee replacement surgeries done using our iTotal CR was 27% less ($p<0.001$) than the average total for surgeries done using an off-the-shelf implant.

As a result, we believe our implants may appeal particularly to surgeons who treat young, active patients. The surgeons might otherwise recommend postponing surgery out of fear that the patient will not be eligible for a revision surgery if one becomes necessary.

Fewer post-operative issues. We believe our customized knee implants reduce the number of post-operative issues. Our review of a retrospective study of 248 total knee replacements, or the 2015 TKA Study, presented at the 2015 ICJR Arthroplasty Conference indicates that patients who received an iTotal CR had significantly lower transfusion rates ($p=0.009$) and adverse event rates at discharge ($p<0.001$) than patients who received an off-the-shelf total knee replacement implant. We provided financial support for this study. One of the authors of this study also is a paid consultant to us. Our review of unpublished research sponsored by us also leads us to believe that use of our iTotal CR is associated with lower adverse event rates during the 90-day period following surgery. The reduction in adverse events observed during the 90-day period following surgery is meaningful because surgeons may not be reimbursed for additional post-operative follow up care during this period.

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Greater efficiency. Because of the simplified surgical procedure used with our products, we believe total operating room time is reduced when implanting an iTotal CR as compared to an off-the-shelf implant. Our summary of the results of a retrospective study of 70 patients who had undergone total knee replacement presented at the 2014 German Congress for Orthopedics and Trauma Surgery indicates that average overall operating room time was statistically significantly reduced (p=0.028) for the group of patients who received an iTotal CR in comparison with patients who received an off-the-shelf knee replacement. We believe surgeons can use these time savings to increase their productivity.

For the hospital. We believe that our customized implants and iFit technology platform provide a better economic outcome for hospitals through:

Improved implant and instrument management and reduced sterilization costs. As a result of our just-in-time delivery model, we ship our knee implants and iJigs to the hospital or other medical facility in advance of the procedure, greatly reducing the need to store implants and instruments in the hospital. In addition, we estimate that a total knee replacement procedure using an off-the-shelf implant requires approximately five to 10 double-tiered, instrument trays, which must be cleaned, sterilized and stored between procedures at significant cost to the hospital. A knee replacement procedure using our iTotal CR product requires only one tray of reusable instruments. As a result of our just-in-time delivery approach and the reduction in the requirements for reusable instruments in procedures using our products compared to an off-the-shelf implant, we believe our products meaningfully reduce a hospital's instrument cleaning, sterilizing and storage costs.

Improved productivity in the OR. We believe that the iJigs we provide with our implants eliminate many of the intraoperative sizing steps and reduce the number of positioning steps necessary with an off-the-shelf product. In addition, our approach of delivering a single-package with pre-sterilized, single-use instruments allows for a more streamlined and efficient operating room through quick and easy set up and tear down. As a result, we believe that knee replacements with our customized total knee implants can improve turnaround times with the potential for more procedures to be completed within the same amount of time and for hospitals to generate additional revenue.

Shorter stays. We believe that our customized total knee replacements may shorten hospital stays. Our summary of the results of the 2015 TKA Study indicates that a statistically significantly greater percentage of patients who underwent total knee replacement were discharged in fewer than three days following surgery (p=0.033) in the iTotal CR group (42%) than in the off-the-shelf group (30%).

Fewer adverse events. Many insurers and third-party payors, including Medicare, require the hospital bear the cost of treating infections and post-operative adverse events if they occur within 90 days following the implant procedure. If instruments are not properly prepared prior to surgery, they are a potential source of costly infections. The lower number of instruments used with our knee implants reduces the possibility of a contaminated instrument. Our summary of the results of the 2015 TKA Study indicates that use of our iTotal CR statistically significantly reduced blood transfusion rates (p=0.009) and adverse event rates at discharge (p<0.001) as compared to an off-the-shelf knee implant.

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Our strategy

Our objective is for our customized implants to become the standard of care for orthopedic joint replacement surgery. We believe that our iFit Image-to-Implant technology platform will enable us to offer a wide variety of customized joint replacement implants with superior performance that offer key clinical and economic benefits over off-the-shelf implants. Key elements of our strategy to achieve our objective are to:

Broaden our product portfolio by launching additional customized orthopedic implants. While our initial focus has been on the knee implant market, we believe our iFit technology platform is applicable to customized implants for all major joints in the body and multiple implant subcategories within each joint. We recently initiated the limited launch of iTotal PS, our posterior-stabilized total knee replacement implant, to address the largest segment of the knee replacement market. In addition, we expect to submit to the FDA in 2015 an application for 510(k) clearance of our iTotal Hip, our first customized hip replacement implant. We also are applying our iFit technology platform to develop additional product opportunities in the knee and hip replacement markets and may seek to apply our iFit technology platform to other orthopedic markets in the longer-term, including shoulder, other extremities, spine and ligament reconstruction.

Expand our sales efforts to drive adoption of our products. We systematically analyze market opportunities by considering factors such as the number of orthopedic surgeons, procedure volumes, pricing and reimbursement. We often seek to penetrate these markets by establishing relationships with influential surgeons who perform a high-volume of joint replacement procedures. We work with these surgeons to educate other surgeons. Our goal is to achieve a minimum ten percent market share in these markets.

Establish the clinical and economic benefits of our products and technologies. We believe our customized knee implant products offer important clinical and economic benefits to patients, surgeons and hospitals. Potential benefits include better function, less bone resection, less blood loss, greater patient satisfaction, reduced length of stay and lower adverse event rates. These potential economic benefits for hospitals also include reduced procedure times and reduced instrument management, cleaning and sterilization costs. We believe that our iFit technology platform will allow us to offer products for other joints that also afford important clinical and economic benefits. We have designed and sponsored studies that support these clinical and economic data. We will continue to establish these potential benefits through the design and sponsoring of studies to increase our available clinical and economic data.

Expand our digitally driven, just-in-time manufacturing processes. We have built state of the art manufacturing processes, including proprietary software and 3D printing capabilities. We are continuing to invest in these processes as we believe they provide us important competitive advantages, including:

large-scale production of customized implants;

shorter product design and development timeframes;

continuous improvement of our products without making obsolete a large inventory of implants and instruments, in contrast to manufacturers of off-the-shelf implants; and

expansion of gross margins through the ongoing vertical integration of our digital manufacturing processes.

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Enhance our patent portfolio and continue to exploit our patent position. We own or exclusively in-license a total of approximately 470 issued patents and pending patent applications that cover customized implants and PSI for all major joints and other elements of our iFit technology platform. We plan to add to this portfolio as we continue to develop new proprietary products and technologies and protect our existing ones.

Our products

Knee replacement products

We offer a broad line of primary knee replacement implants, both partial and total, that we customize to fit each particular patient. Surgeons use our family of customized knee implants to treat mild to severe osteoarthritis of the knee. All of our knee replacement products have been cleared by the FDA under the premarket notification process of Section 510(k) of the FDCA and have received certification to CE Mark. We deliver our customized knee replacement implants and iJigs, together with iView, to the hospital in a single pre-sterilized package in advance of the scheduled arthroplasty procedure.

The following is an overview of each of our knee replacement implant products:

iTotal CR is the only cruciate-retaining, customized total knee replacement system on the market designed to restore the natural shape of a patient's knee. We introduced the iTotal CR in May 2011 and launched new generations in each of 2012, 2013 and 2015. The iTotal CR includes a femoral implant, a tibial tray, and dual medial and lateral polyethylene inserts, which serve as a cushion between the femoral and tibial components, all of which are individually made for the particular patient, together with a polyethylene patella designed to work with our customized components.

The iTotal PS is the only posterior cruciate ligament substituting, or posterior-stabilized, customized total knee replacement product on the market designed to restore the natural shape of a patient's knee. We initiated a limited launch of the iTotal PS in the United States in February 2015, which we expect will continue into 2016. The iTotal PS includes a femoral implant with a metal cam, a tibial tray, and a single polyethylene insert, which includes a plastic spine, all of which are individually made for the particular patient, together with a polyethylene patella designed to work with our customized components.

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The iDuo is the only customized bicompartmental knee replacement system on the market. The iDuo is considered a bicruciate-retaining knee replacement because the surgeon may retain both the anterior cruciate ligaments, or ACL, and posterior cruciate ligaments, or PCL. We first launched the iDuo in December 2007 and have launched new generations of the product in each of 2010 and 2012. The iDuo includes a femoral implant, a tibial tray and a single polyethylene insert, all of which are individually made for the particular patient, together with a polyethylene patella designed to work with our customized components.

The iUni is the only customized unicompartmental knee replacement product on the market for treatment of the medial or lateral compartment of the knee. The iUni is considered a bicruciate-retaining knee replacement because the surgeon retains both the ACL and PCL. We first launched the iUni in June 2007 and launched new generations of the product in each of 2009 and 2012. The iUni includes a femoral implant, a tibial tray and a single polyethylene insert, all of which are individually made for the particular patient.

Hip replacement product candidate

iTotal Hip

We are currently developing our iTotal Hip to provide a customized total hip replacement implant. We expect to submit to the FDA an application for 510(k) clearance of our iTotal Hip in 2015. We expect that iTotal Hip will be our next product introduction after iTotal PS. We believe the introduction of iTotal Hip will provide synergies with our existing line of customized knee implants because most surgeons who perform knee replacements also perform hip replacements. Thus, we expect that iTotal Hip will complement our existing product line, customer base, sales force and distribution channels.

Problems with off-the-shelf hip implants. As with the knee, no two hips are the same. They vary in size and shape. As is the case for knee replacements, off-the shelf hip replacement implants are offered in a limited number of standard shapes and sizes. The key clinical challenges and complications with off-the-shelf total hip replacements are:

Implant dislocation. Hip implant dislocation occurs when the head of the femoral component dislodges from the hip socket component, which is referred to as the acetabular component, or hip cup. This can result from one or more of the following:

an inappropriate angle between the stem and the neck of the femoral component, referred to as neck angle;

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improper neck length;

an inappropriate forward angle, referred to as anteversion, of the neck; and

improper placement of the hip cup, which can include an incorrect forward angle.

Leg length discrepancy. Leg length discrepancy occurs when one leg of the patient is longer than the other post-surgery. This can result from a neck angle or femoral component length that is substantially different from the patient's native anatomy or from incorrect placement of the femoral component. Leg length discrepancy can lead to pain and muscle fatigue and is a frequent cause of patient complaints.

Manufacturers of off-the-shelf hip implants attempted to address these shortcomings by developing modular hip systems consisting of a large number of neck components with different neck angles, lengths and anteversion paired with off-the-shelf stems and femoral head components. The surgeon would select a modular neck during surgery that best fit the patient's anatomy. Following their introduction, these modular hips initially were widely used. However, there was a high failure rate because the implants had a tendency to break at the modular connection between the stem and the neck and corrode because of the additional metal-to-metal connection between the neck and the stem. As a result, usage of modular hips has declined dramatically.

Off-the-shelf hip implants require a large number of trays of reusable instruments with the same instrument management challenges and costs of cleaning and sterilization associated with off-the-shelf knee implants. In addition, orthopedic surgery using off-the-shelf hip implants is characterized by a difficult surgical technique and can suffer from a lack of reproducibility in component placement.

The ConforMIS hip replacement solution. We are developing our iTotal Hip using our iFit technology platform. Our iTotal Hip will be customized to the individual patient and designed to address the limitations of off-the-shelf hip implants. We are designing our iTotal Hip to consist of the following components:

a femoral component made of a single metal piece, or monoblock, that incorporates both stem and neck, which includes a customized neck angle and length designed to match the patient's native anatomy, along with a standard head;

a hip cup along with a polyethylene acetabular liner; and

a set of single-use, patient-specific acetabular and femoral iJigs for placement of the acetabular and femoral components with the proper anteversion to both the femur and the hip cup.

We believe that our customized iTotal Hip monoblock femoral component has the same strength as the femoral component of a standard monoblock, or non-modular, off-the-shelf hip implant while at the same time addressing the variability of patients' femoral neck shapes. We believe that the customized nature of our implant will appeal to many surgeons who used modular hips in the past. In addition, we believe the combination of our customized implant paired with patient-specific iJigs and patient-specific placement of the acetabular cup and the femoral component will help address the problems of hip dislocation and leg length discrepancy associated with off-the-shelf implants.

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Because our iTotal Hip is based on our iFit technology platform, we are designing it to take advantage of our proprietary design software, 3D printing technology and a just-in-time single package delivery system, just as we do with our customized knee implants.

Our proprietary iJigs

Our iJigs are customized, single-use, patient-specific instrumentation. The iJigs we deliver with our joint replacement products include the guides and instruments the surgeon requires to remove the bone and soft tissue necessary to fit our customized implant to the patient. We believe that providing our iJigs with our customized knee implants enable a more accurate, reproducible and simplified surgical procedure by reducing the number of steps and increasing the precision of the alignment.

In an off-the-shelf procedure, the surgeon must have large numbers of reusable instruments available because the surgeon does not know in advance which bone cuts and other tissue removal will be necessary to prepare the patient to receive the off-the-shelf implant. As a result, a knee replacement procedure performed using our customized implants and iJigs requires only one tray of reusable instruments, which we provide to the hospital, as compared to a knee replacement procedure using an off-the-shelf implant, which requires approximately five to 10 double-tiered, reusable instrument trays, which the off-the-shelf manufacturer provides to the hospital. We provide our implants with a full set of iJigs in a single package. Our iJigs arrive sterile and are discarded after use.

The graphic below depicts our single package delivery systems for our iJigs and knee replacement products:

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Clinical studies

In evaluating the clinical and economic benefits of our customized knee implants, we consider results obtained from studies sponsored by us, conducted by orthopedic surgeons who are paid consultants to us and conducted independently by orthopedic surgeons, including studies that compare our customized knee implants with off-the-shelf knee implants. As of May 31, 2015, there were 5 peer-reviewed journal articles and 24 abstracts either presented or accepted for presentation at conferences reporting on the results of clinical studies of our customized knee implants. Of the published or presented studies known to us that compared our knee replacement product to an off-the-shelf product, all but one reported either that the performance of our knee replacement product was superior to an off-the-shelf product on the reported measures or that there were no statistically significant differences detected between the performance of our knee replacement product and an off-the-shelf knee replacement product on those measures. The following provides our summary of the findings of several of these studies that relate to our iTotal CR product and that we considered in forming our views as to the clinical and economic benefits of our customized knee implants:

Lower adverse event rates and faster hospital discharge. We reviewed an abstract presented at the 2015 ICJR Arthroplasty Conference that described a retrospective study of 248 patients who had undergone a total knee replacement, 126 of whom received an iTotal CR and 122 of whom received a posterior cruciate-retaining off-the-shelf knee replacement. Our summary of the principal findings of the study is as follows:

- patients in the iTotal CR group showed statistically significantly lower blood transfusion rates ($p=0.009$) and adverse event rates at discharge ($p<0.001$) as compared to patients in the off-the-shelf implant group;
- risk-adjusted odds ratios indicated that patients in the off-the-shelf implant group were 4 times more likely to experience a blood transfusion and 3.7 times more likely to have an adverse event than patients in the iTotal CR group;
- a statistically significantly greater percentage ($p=0.033$) of patients in the iTotal CR group (42%) were discharged in fewer than three days following surgery than patients in the off-the-shelf group (30%);
- when discharge disposition was analyzed, a statistically significantly lower percentage ($p<0.001$) of patients in the iTotal CR group were discharged to acute care facilities as compared to patients in the off-the-shelf implant group; and
- there was a greater than $800 total cost of care savings per patient in the iTotal CR group compared to patients in the off-the-shelf implant group after including the estimated average cost of the pre-operative CT scan for patients in the iTotal CR group, primarily due to the assumed savings resulting from the more favorable discharge disposition of patients in the iTotal CR group compared to patients in the off-the-shelf implant group.

We provided financial support for this study.

Improved clinical outcomes and greater patient satisfaction. We reviewed an abstract presented at the 2015 ICJR Arthroplasty Conference that described an investigator-initiated, matched-pair, retrospective study of 35 patients who had undergone total knee replacement with an iTotal CR and 35 patients who had undergone total knee replacement with an off-the-shelf knee implant. Two surgeons performed these TKAs. For each matched pair, the same surgeon performed

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the iTotal CR and off-the-shelf procedure. Our summary of the principal findings of the study is as follows:

- patients in the iTotal CR group had statistically significantly faster recovery times ($p<0.001$) than patients in the off-the-shelf implant group as measured by the average time to complete specified functional activities, such as walking and climbing stairs;

- patients in the iTotal CR group suffered statistically significantly less blood loss than patients in the off-the-shelf implant group, as measured by the differences in average drop in blood hemoglobin at one day ($p<0.001$), five days ($p=0.002$) and ten days ($p=0.03$) post-procedure;

- the average self-reported satisfaction score of patients in the iTotal CR group was 94.3%, compared to 74.2% for the group of patients in the off-the-shelf group, and this difference was statistically significant ($p=0.04$); and

- the average KOOS, or Knee injury and Osteoarthritis Outcome Score, of patients in the iTotal CR group was 83.0%, compared to 73.7% for the group of patients in the off-the-shelf group, and this difference was statistically significant ($p=0.037$). KOOS is a validated, self-administered testing instrument used to assess patient outcomes.

This study was conducted by independent orthopedic surgeons.

Favorable adverse event rate and outcomes. We reviewed an abstract that has been accepted for presentation at the upcoming 2015 International Congress for Joint Reconstruction Pan-Pacific Congress that described a multi-center, prospective study of adverse event rates and outcome scores of 197 patients who had undergone total knee replacement with an iTotal CR. Our summary of the principal findings of the study is as follows:

- the adverse event rate, which included manipulations under anesthesia, or MUA, a procedure used post-operatively to adjust a knee replacement implant to improve its function, transfusions and revisions rates, compared favorably to the adverse event rates reported in separate multi-center studies published on off-the-shelf implants;

- the cumulative rate of MUA was 2.55%, which compared favorably to the 4.6% rate of MUA reported in a separate multi-center study of off-the-shelf implants;

- range of motion was slightly reduced from baseline at six weeks post-operatively, but significantly improved from baseline at six months ($p<0.001$) and one year ($p=0.001$) post-operatively; and

- patients demonstrated statistically significant improvements from baseline scores ($p<0.05$) on the KOOS and on the objective, function and satisfaction portions of the 2011 Knee Society Knee Scoring System, or KSS, by the six-week time-point, with continued improvement reported at the one-year follow up visit. KSS is a validated testing instrument used to assess patient outcomes.

We provided financial support for this study. All of the authors of this study are paid consultants to us or have been paid by us for specified services.

More accurate alignment. We reviewed a paper published in 2014 in the *Journal of Arthroplasty* that described an investigator-initiated, retrospective study of 200 patients who had undergone total knee replacements, 100 of whom received an iTotal CR implant and 100 of whom received an off-the-shelf implant. The same surgeon performed all 200 implant procedures, and all

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of the iTotal CR and off-the-shelf implants had been performed consecutively. Our summary of the principal findings of the study is as follows:

- our iJigs provided a statistically significant improvement in mechanical axis alignment ($p<0.002$) and positioning of the front of the femoral component ($p=0.032$) compared to the process used in an off-the-shelf total knee replacement;
- patients in the 110 iTotal CR group were 1.8 times more likely to have proper femoral component mechanical alignment as compared to patients in the off-the-shelf group; and
- there was no difference seen on the measure of rotation of the tibial component.

This study was conducted by five independent orthopedic surgeons and one surgeon who is a paid consultant to us.

A more stable knee implant without abnormal lift off. We reviewed an abstract presented at the 2014 ICJR Pan-Pacific Congress that described a study of 20 patients who had undergone total knee replacement, 11 of whom received an iTotal CR implant and nine of whom received an off-the-shelf knee implant. The same surgeon performed all 20 implant procedures. All patients had been assessed following the procedure on the Knee Society Knee Score, a commonly used surgeon-assessed weighted score of pain, stability, range of motion and function. Our summary of the principal findings of the study follows. All of the patients had Knee Society Knee Scores greater than 90 out of a maximum score of 100, which is an indication of a clinically successful knee replacement. Patients who had received an iTotal CR showed a post-operative kinematic pattern similar to a normal knee when asked to perform a deep knee bend and chair-rise. Patients with off-the-shelf implants experienced greater variability in their kinematic patterns, differing from the typical kinematic patterns of the normal knee. More than half of the patients with an off-the-shelf implant experienced abnormal lift off, while patients with an iTotal CR showed no lift off. Due to the small sample size, the results from this study were not statistically significant. We provided financial support for this study. Two of the surgeons who conducted this study are paid consultants to us.

Improved function with a more normal kinematic pattern. We reviewed an abstract presented at the 2014 ICJR Pan-Pacific Congress that described a study of 20 patients who had undergone a total knee replacement, 10 of whom received an iTotal CR implant and 10 of whom received an off-the-shelf knee implant. The same surgeon performed all 20 implant procedures. Our summary of the principal findings of the study follows. Patients who received an iTotal CR achieved more normal-like kinematic patterns. During both a deep knee bend and a chair-rise, patients with an iTotal CR achieved more normal motion of their lateral condyle and greater magnitude of axial rotation. One-half of the patients with off-the-shelf implants experienced an anterior slide of their lateral condyle, which is the opposite of normal knee kinematics. Due to the small sample size, the results from this study were not statistically significant. We provided financial support for this study. One of the authors of this study also is a paid consultant to us.

Sales and marketing

We market and sell our products in the United States, Austria, Germany, Ireland, the United Kingdom, Switzerland, Hong Kong and Singapore. See our "Management's Discussion and Analysis of Financial Condition and Results of Operations Consolidated results of operations Revenue" section of this prospectus for a summary of product revenue by geography. We market our products to orthopedic surgeons, hospitals and other medical facilities, including ambulatory surgery centers, and patients. We have 87 employees in the United States and other countries engaged in the sales and marketing of our products, of which 70 are direct sales representatives. We use independent sales representatives and a limited number of distributors to complement our own sales and marketing efforts in these and other markets. We expect to expand

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the size of our sales and marketing capabilities through additional hires and by entering into additional distribution arrangements in key territories.

We offer technical and product focused training programs for our direct sales, independent sales and distributor representatives. We have designed these programs to provide the entire sales force with technical expertise and product knowledge so they may more effectively represent and market our products to surgeons, hospitals and other medical facilities. We believe we offer a simplified surgical technique with the use of our products that may reduce the need for our representatives to spend time in the operating room during a procedure when compared to the representatives of off-the-shelf implant manufacturers. This potentially will allow our sales representatives to spend more time on new customer growth opportunities.

We believe surgeons appreciate the clinical and economic benefits, including increased patient satisfaction, operating room efficiencies and lower adverse event rates, that we believe our products offer. We believe hospitals focus on the economic benefits that we believe are associated with our products, such as fewer instrument trays to manage, clean and sterilize, reduced operating room time, faster operating room set up and breakdown time and lower adverse event rates. We believe patients are interested in returning to daily activities quickly and are attracted to our customized approach. We employ direct-to-consumer marketing, primarily through patient testimonials, social media, search engine marketing, and print, online, radio and television news reports.

In the United States, we use a database of surgeons, hospitals and procedure volumes to determine which geographical regions are most commercially attractive. Globally, we look for markets with a high volume of total knee replacements, favorable reimbursement characteristics and an historical openness to advanced technologies. We deploy sales representatives to focus on surgeons in these markets. In regions with a lower volume of total knee replacements, we generally contract with independent sales representatives and distributors to take advantage of their broad networks, surgeon relationships and ancillary, non-competitive, product lines such as sports medicine products.

We work with orthopedic surgeons, including select key opinion leaders, affiliated with leading medical centers in the United States and Germany. We refer to the medical centers at which these surgeons practice as ConforMIS Centers of Excellence, or COE. We work with the COE surgeons on technical training and surgeon education. We plan to selectively add COEs on an ongoing basis.

We identify local markets in the United States in which we believe we can become a top-three orthopedic implant supplier, as measured by procedures. We work to significantly increase our sales in these markets by focusing on high-volume, influential surgeons who use our products. We create a tailored direct marketing strategy to increase consumer awareness in these markets. We believe we have achieved a greater than 10% share by volume of procedures in a number of these markets.

Research and development

Our internal research and development efforts are focused on continued innovation to develop customized implants for the knee and hip and to assess the application of our iFit technology platform to other major joints in the body. In our research and development activities, we actively work on:

- new product development;
- enhancements of existing products and software;

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improvements in our iFit technology platform to further advance production efficiency and decrease the production time from receipt of an order and CT scan to delivery of our product; and

advancements of our iFit technology platform that will enable us to provide our customized products to a larger customer base, which we refer to as mass customization.

Our team of 33 full-time research and development employees has extensive experience in biomechanical engineering, manufacturing engineering and software engineering and development. A significant portion of our research and development activities involves the development of proprietary algorithms and computer software that underpins our entire iFit technology platform.

When we develop a new product or seek to improve our existing products, our team of biomechanical and software engineers typically collaborates closely with experienced orthopedic surgeons and other independent scientists. After we complete the development of a new product or an improvement to an existing product, we seek regulatory clearance before introducing the product into patients.

Manufacturing

We conduct our manufacturing activities in state-of-the-art design and manufacturing facilities in Bedford, Burlington and Wilmington, Massachusetts. We are in the process of vacating our Burlington facility and transferring those operations to our Wilmington facility. We have 158 full-time employees on our manufacturing team.

We produce all of our CAD designs in-house and use them to direct all of our product manufacturing efforts. We manufacture all of our patient-specific instruments, or iJigs, in our facilities. We also make the majority of the tibial components used in our implants at our facilities. We outsource the production of the remainder of the tibial components and the manufacture of femoral and other implant components to third-party suppliers. The femoral components of our implants are cast in metal and finished. Our suppliers make our customized implant components using the CAD designs we supply.

We have established a diverse, approved supplier base that is skilled in medical device manufacturing. Our suppliers are primarily based in the United States. We do not have any long-term supply arrangements and purchase our supplies on a purchase order basis. We maintain a dual source capability for our purchased implant components in an effort to ensure supply reliability, flexibility and cost competitiveness. For certain raw materials, including the powders used for our 3D printing, we rely on sole source providers who service large portions of the markets for these materials.

In the future, if and as the volume of our product sales increases, we expect to take the following steps in connection with our manufacturing activities:

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

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

develop 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

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

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We also plan to explore other opportunities to reduce our manufacturing costs.

iFit 3D printing

We believe that 3D printing is especially suited for production of our individually designed implants and instruments. We focus on 3D printing as a key element of our manufacturing because we believe it enables fast, cost-effective, and scalable processes that will deliver high quality implants and instruments customized to fit the unique anatomy of each patient. As a result, 3D printing plays a key and increasing role in our manufacturing operations.

We currently apply our iFit 3D printing technology to manufacture iJigs using computer-controlled lasers that melt polymer powders into a solid on a layer-by-layer basis until the entire part is completed. The process of melting powders into a solid is called sintering. We use selective laser sintering, or SLS, with approved polymer powders to manufacture plastic components for our iJigs.

We have received FDA clearance to apply our iFit 3D printing technology to manufacture the metal femoral implant component for our iTotal CR using direct metal laser sintering, or DMLS, using raw material that meets or exceeds the ASTM F-75 specification for chemical content and mechanical properties. ASTM F-75 is the accepted material standard for knee replacement femoral components. We plan to scale-up our 3D printing of the femoral component of our iTotal CR beginning in 2015.

We expect to use a portion of the net proceeds of this offering to significantly expand our 3D printing capacity. Because we are able to operate our 3D printers on a near continuous basis with a limited workforce and can add 3D printing capacity without large incremental infrastructure investments, we believe that we will see additional per unit cost savings as we scale-up our manufacturing using 3D printing.

Quality assurance

We apply a variety of automated and manual quality controls to our iJigs, implant components and other instruments we supply to ensure that our products conform to their specifications. Members of our quality department also inspect our devices at various steps during the manufacturing cycle to facilitate compliance with specifications. Our quality department periodically audits our suppliers to ensure conformity with our specifications and with our policies and procedures for our devices.

We and our suppliers are subject to extensive regulation by the FDA under its Quality System Regulations, or QSR. The QSR provide that manufacturers must establish and follow quality systems consistent with the QSR framework to ensure that their products consistently meet applicable requirements and specifications. In accordance with the QSR framework, we have validated or verified the processes used in the manufacturing and testing of our devices. Our Burlington and Bedford manufacturing facilities are FDA registered, and we believe they are compliant with the FDA's QSR. We are in the process of completing our validations of our Wilmington facility and expect to register the facility with the FDA in the second quarter of 2015. We have also received certification from the British Standards Institution, or BSI, a Notified Body to the International Standards Organization of our quality system. Certification by a Notified Body is a necessary element of obtaining CE Marking in the EU. We are subject to periodic, announced and unannounced inspections by BSI, the FDA, and other governmental agencies. We continue to monitor our quality system and management efforts in order to maintain our overall level of compliance. See " Regulatory requirements" below.

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Intellectual property

Protection of our intellectual property is an important priority for our company. Our success depends in part on our ability to obtain and maintain proprietary rights for our products and technology, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our intellectual property position by, among other things, filing U.S. and certain foreign patent applications related to our products and technology where patent protection is available. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We typically seek patents on inventions relating to customized implants and iJigs, and on their methods of manufacture. We generally file patent applications in the United States, the major markets in the EU, and in select other commercially important countries. We typically rely on trade secret protection for our proprietary algorithms that we use to design customized implants and iJigs.

Patent rights

As of May 31, 2015, we owned or exclusively in-licensed 163 issued patents around the world, including 112 patents issued in the United States and 51 foreign patents.

With respect to the patents that we own relating primarily to our customized joint replacement implants, the first nonprovisional application was filed in 2002 claiming priority to a provisional application filed in 2001 and is expected to expire in 2022 and the other patents are expected to expire between 2022 and 2030.

With respect to the patents that we own relating primarily to our patient-specific instrumentation, the first nonprovisional application was filed in 2002 claiming priority to a provisional application filed in 2001 and is expected to expire in 2022 and the other patents are expected to expire between 2022 and 2031.

With respect to the patents that we own relating primarily to our iFit technology platform, the first nonprovisional application was filed in 2002 claiming priority to a provisional application filed in 2001 and is expected to expire in 2022 and the other patents are expected to expire between 2022 and 2032.

With respect to the patents that we exclusively in-license, the first nonprovisional application was filed in 2000 claiming priority to a provisional application filed in 1998 and is expected to expire in 2019 and the other patents are expected to expire between 2019 and 2021.

As of May 31, 2015, we owned or exclusively in-licensed 309 patent applications, including 122 patent applications pending in the United States and 187 foreign patent applications.

With respect to the patent applications that we own relating primarily to our customized joint replacement implants, patient-specific instrumentation, and our iFit technology, the first were filed in 2001 and if patents issue on these applications, they would be expected to expire in 2022 and if patents issued on the other patent applications, such patents would be expected to expire between 2023 and 2035.

With respect to the patent applications that we exclusively in-license, the first was filed in 1998 and if a patent issues on this application, it would be expected to expire in 2019. If patents issue on the other patent applications, such patents would be expected to expire between 2019 and 2026.

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Our patent portfolio covers a range of subject matter, including:

- customized articular implants for the knee, hip, spine, shoulder, ankle and extremities;
- customized instrumentation including for joint replacement and ligament reconstruction;
- imaging technology;
- 3D printing technology for implants and instruments;
- methods of designing customized implants and instruments; and
- methods of manufacturing customized implants and instruments.

Licenses from others

We are a party to several agreements under which we have licensed rights in certain patents, patent applications and other intellectual property. We enter into these agreements to augment our proprietary intellectual property portfolio. The licensed intellectual property covers some of the products that we are researching, developing and commercializing and some of the technologies that we use. These licenses impose certain license fee, royalty payment and diligence obligations on us. We expect to continue to enter into these types of license agreements in the future. We do not believe that any of these licenses are material to our business.

Patent litigation

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations.

Our business success will depend in part on our not infringing the intellectual property rights of others, including patents issued to our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture and sale of such potential products could be severely restricted or prohibited. In addition, our competitors may independently develop similar technologies. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to protect our intellectual property rights.

Licenses to others

In September 2013, we filed suit in the U.S. District Court, District of Massachusetts against Wright Medical Technology, Inc., or Wright Technology, a wholly owned subsidiary of Wright Medical Group, Inc., or Wright Group. We refer to Wright Technology and Wright Group collectively as Wright Medical. The lawsuit alleged that Wright Technology's PROPHECY® knee and ankle systems infringe four of our patents. In January 2014, Wright Group transferred its orthopedic reconstruction division to Micro-Port Orthopedics, Inc., or MicroPort, a wholly owned subsidiary of MicroPort Scientific Corporation. In February 2014, we filed an amended complaint, naming MicroPort as an additional defendant, and alleging infringement by both defendants of an additional patent. We settled this lawsuit against Wright Medical and MicroPort in April 2015. As part of the settlement, we granted to MicroPort and Wright Medical the licenses described below. We believe that MicroPort and Wright Medical also entered into a separate indemnification agreement related to the licensed products transferred to MicroPort in January 2014.

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License agreement with MicroPort

In April 2015, we entered into a worldwide license agreement with MicroPort. 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. 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.

License agreement with Wright Medical

In April 2015, we entered into a non-exclusive, fully paid up, worldwide license agreement with 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 the patents and patent applications licensed to Wright Medical, which currently is expected to occur in 2030.

Trademarks

As of May 31, 2015 we have filed 130 trademark registrations in the United States and in other major markets worldwide, including the following marks: ConforMIS, iFit, iTotal, iDuo, and iUni. We have 43 trademark applications pending in the United States and in other major markets worldwide.

Competition

The joint replacement industry is intensely competitive, subject to rapid change and sensitive to the introduction of new products or other market activities of industry participants. We face competition from many different sources, including major medical device companies.

We compete with several large, well-known companies that dominate the market for orthopedic products, principally LVB Acquisition, Inc., doing business as Biomet Group, Inc., or Biomet, Zimmer Holdings, Inc., or Zimmer, which is expected to acquire Biomet in 2015, DePuy Orthopedics, Inc., or DePuy, a Johnson & Johnson company, Smith & Nephew, Inc., or Smith & Nephew, Stryker Corporation, or Stryker, and MicroPort. These competitors have significantly greater financial resources, larger sales forces and networks of distributors, a greater number of established relationships, some of which may be exclusive, with key orthopedic surgeons, hospitals and third-party payors, and greater experience in research and development, manufacturing, obtaining regulatory clearances and marketing approved products than we do. These companies also compete with us in acquiring technologies complementary to, or necessary for, the development of our products and recruiting and retaining qualified scientific, engineering and management personnel.

We also compete with numerous other companies that are developing and marketing competitive joint replacement products, as well as companies exploring alternatives to joint replacement such as biologic cartilage repair systems.

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We believe that the principal factors on which we compete with others in our market include:

- the ability to introduce innovative products that are differentiated from competitors' offerings and represent an improvement over currently available products;
- the ease of use of the products and the quality of training, services and clinical support provided to surgeons and hospitals;
- the safety and efficacy of products and procedures, as demonstrated in published studies and other clinical reports;
- the ability to anticipate and meet customers' needs and commercialize new products in a timely manner;
- acceptance and adoption of products by patients, physicians and hospitals; and
- the price of products and cost effectiveness of the procedure and availability and rate of third-party reimbursement.

The prices that we charge our customers for our products vary from customer to customer based on such factors as the volume of product being purchased, geographic region, reimbursement environment and competitive factors. We believe that our current pricing for our products generally is within the same range as that of our principal competitors.

Regulatory requirements

Our products are medical devices that are subject to extensive regulation by government authorities in the United States and in other countries and jurisdictions, including the EU. These governmental authorities regulate the marketing and distribution of medical devices in their respective geographies. The regulations cover the entire life cycle of the product, including the research, development, testing, manufacture, quality control, packaging, storage, labeling, advertising and promotion of the devices. In addition, post-approval monitoring and reporting, as well as import and export of medical devices, are subject to regulatory requirements. The processes for obtaining regulatory approvals or clearances in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

Review, approval and clearance of medical devices in the United States

Medical devices in the United States are strictly regulated by the FDA. Under the FDCA a medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Unless an exemption applies, a new medical device may not be marketed in the United States unless it has been cleared by the FDA through filing of a 510(k) premarket notification, or 510(k), or approved by the FDA pursuant to a premarket approval application, or PMA. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes depending on the level of control necessary to assure the safety and effectiveness of the device. Class I devices have the lowest level or risk associated with them, and are subject to general controls, including labeling, premarket notification and adherence to the

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QSR. Class II devices are subject to general controls and special controls, including performance standards. Class III devices, which have the highest level of risk associated with them, are subject to most of the aforementioned requirements as well as to premarket approval. Most Class I devices and some Class II devices are exempt from the 510(k) requirement, although manufacturers of these devices are still subject to registration, listing, labeling and QSR requirements.

To date, we have used exclusively the 510(k) premarket notification process to obtain regulatory clearance from the FDA for the marketing and sale of our joint replacement products in the United States. All of our currently marketed products are Class II devices marketed pursuant to 510(k) clearances. We expect that our iTotal Hip product will be classified as a Class II device for which we will seek 510(k) clearance.

510(k) premarket notification

A 510(k) is a premarket submission made to the FDA to demonstrate that the proposed device to be marketed is at least as safe and effective (i.e., substantially equivalent) to another legally marketed device, or predicate device, that did not require premarket approval. In evaluating a 510(k), the FDA will determine whether the device has the same intended use as the predicate device, and (a) has the same technological characteristics as the predicate device, or (b) has different technological characteristics, and (1) the data supporting substantial equivalence contains information, including appropriate clinical or scientific data, if deemed necessary by the FDA, that demonstrates that the device is as safe and as effective as a legally marketed device, and (2) does not raise different questions of safety and effectiveness than the predicate device. Most 510(k)s do not require clinical data for clearance, but the FDA may request such data.

The FDA seeks to review and act on a 510(k) within 90 days of submission, but it may take longer if the agency finds that it requires more information to review the 510(k). If the FDA concludes that a new device is not substantially equivalent to a predicate device, the new device will be classified in Class III and the manufacturer will be required to submit a PMA to market the product. With the enactment of the Food and Drug Administration Safety and Innovation Act, or the FDASIA, a de novo pathway is directly available for certain low to moderate risk devices that do not qualify for the 510(k) pathway due to the absence of a predicate device.

Modifications to a 510(k)-cleared medical device may require the submission of another 510(k) or a PMA if the changes could significantly affect safety or effectiveness or constitute a major change in the intended use of the device. Modifications to a 510(k)-cleared device frequently require the submission of a traditional 510(k), but modifications meeting certain conditions may be candidates for FDA review under a Special 510(k). If a device modification requires the submission of a 510(k), but the modification does not affect the intended use of the device or alter the fundamental technology of the device, then summary information that results from the design control process associated with the cleared device can serve as the basis for clearing the application. A Special 510(k) allows a manufacturer to declare conformance to design controls without providing new data. When the modification involves a change in material, the nature of the "new" material will determine whether a traditional or Special 510(k) is necessary.

Premarket approval application

The PMA process for approval to market a medical device is more complex, costly and time consuming than the 510(k) clearance procedure. A PMA must be supported by extensive data, including technical, preclinical, clinical, manufacturing, control and labeling information, that demonstrate the safety and effectiveness of the device for its intended use. After a PMA is submitted, the FDA has 45 days to determine whether it is sufficiently complete to permit a substantive review. If the PMA is complete, the FDA will file the PMA. The FDA is subject to performance goal review times for PMAs and may issue a decision letter as a first action on a PMA

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within 180 days of filing, but if it has questions, it will likely issue a first major deficiency letter within 150 days of filing. It may also refer the PMA to an FDA advisory panel for additional review, and will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the QSR, either of which could extend the 180-day response target. In addition, the FDA may request additional information or request the performance of additional clinical trials before it will reconsider the approval of the PMA or as a condition of approval, in which case the trials must be completed after the PMA is approved.

If the FDA's evaluations of both the PMA and the manufacturing facilities are favorable, the FDA will either issue an approval letter authorizing commercial marketing or an approvable letter that usually contains a number of conditions that must be met in order to secure final approval. If the FDA's evaluations are not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The agency may determine that additional clinical trials are necessary, in which case the PMA approval may be delayed while the trials are conducted and the data acquired are submitted in an amendment to the PMA. Even with additional trials, the FDA may not approve the PMA application. The PMA process, including the gathering of clinical and nonclinical data and the submission to and review by the FDA, can take several years, and the process can be expensive and uncertain. Moreover, even if the FDA approves a PMA, the agency can impose post-approval conditions that it believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. After approval of a PMA, a new PMA or PMA supplement may be required for a modification to the device, its labeling or its manufacturing process. None of our products are currently approved under a PMA approval.

Investigational device exemption

A clinical trial is typically required for a PMA and, in a small percentage of cases, the FDA may require a clinical study in support of a 510(k) submission. A manufacturer that wishes to conduct a clinical study involving the device is subject to the FDA's Investigational Device Exemption, or IDE, regulation. The IDE regulation distinguishes between significant and nonsignificant risk device studies and the procedures for obtaining approval to begin the study differ accordingly. Also, some types of studies are exempt from the IDE regulations. A significant risk device presents a potential for serious risk to the health, safety, or welfare of a subject. Significant risk devices are devices that are substantially important in diagnosing, curing, mitigating or treating disease or in preventing impairment to human health. Studies of devices that pose a significant risk require both FDA approval and an approval of an independent institutional review board, or IRB, prior to initiation of a clinical study. Nonsignificant risk devices are devices that do not pose a significant risk to the human subjects. A nonsignificant risk device study requires only IRB approval prior to initiation of a clinical study.

An IDE application is considered approved 30 days after it has been received by the FDA, unless the FDA otherwise informs the sponsor prior to 30 calendar days from the date of receipt, that the IDE is approved, approved with conditions, or disapproved. The clinical trial must be conducted in accordance with applicable regulations, including but not limited to the FDA's IDE regulations and current good clinical practices. A clinical trial may be suspended by the FDA, the IRB or the sponsor at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the trial.

To date, none of our submissions to the FDA have required the submission of clinical data. However, we have conducted and continue to conduct numerous post-market studies aimed at demonstrating the benefits of our customized knee replacement systems as compared to traditional off-the-shelf systems.

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Post-marketing restrictions and enforcement

After a device is placed on the market, numerous regulatory requirements apply. These include: compliance with the QSR; labeling regulations, which prohibit the promotion of products for uncleared or unapproved or "off-label" uses and impose other restrictions on labeling; and medical device reporting obligations, which require that manufacturers investigate and report to the FDA adverse events, including deaths, or serious injuries that may have been or were caused by a medical device and malfunctions in the device that would likely cause or contribute to a death or serious injury if it were to recur.

The failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: warning letters; fines, injunctions, and civil penalties; recall or seizure of our products; operating restrictions, partial suspension or total shutdown of production; refusal to grant 510(k) clearance or PMA approvals of new products; withdrawal of 510(k) clearance or PMA approvals; and criminal prosecution. To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of subcontractors.

Review and approval of medical devices in the EU

The European Union, or EU, consists of 28 member states and has a coordinated system for the authorization of medical devices. The EU Medical Devices Directive (Council Directive 93/42/EEC, as amended) sets out the basic regulatory framework for medical devices in the European Union. In the EU our medical devices must comply with the Essential Requirements in Annex I to the EU Medical Devices Directive, which we refer to as the Essential Requirements. Compliance with these requirements is a prerequisite to be able to affix the Certificate of Conformity mark, or CE Mark, to our medical devices, without which they cannot be marketed or sold in the European Economic Area, or EEA. To demonstrate compliance with the Essential Requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue a CE Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure requires the intervention of a third-party organization designated by competent authorities of an EU country to conduct conformity assessments, which is referred to as a Notified Body. The Notified Body would typically audit and examine products' technical file and the quality system for the manufacture, design and final inspection of the devices before issuing a CE Certificate of Conformity demonstrating compliance with the relevant Essential Requirements.

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. The Notified Body that has conducted conformity assessments with respect to our joint replacement products is the BSI.

Medical device manufacturers must carry out a clinical evaluation of their medical devices 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 devices being assessed, scientific literature from similar

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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 devices, the Notified Body will review the manufacturer's clinical evaluation process, assess the clinical evaluation data of a representative sample of the devices' 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. The conduct of clinical studies to obtain clinical data that might be required as part of the described clinical evaluation process can be expensive and time-consuming. To date, we have not been required to conduct any of these clinical studies to obtain clinical data as part of the clinical evaluation process.

Even after we receive a CE Certificate of Conformity enabling us to affix the CE Mark on a product and to sell our product in the EEA countries, 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 of Conformity and the recall or withdrawal of our product from the market in the EU, which would prevent us from generating revenue from sales of that product in the EEA. Moreover, each CE Certificate of Conformity is valid for a maximum of five years, but more commonly three years. Our current CE Certificates of Conformity are valid through August 5, 2016 for our iTotal CR product, February 12, 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 of Conformity. There may be delays in the renewal of the CE Certificate of Conformity 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 of Conformity.

In addition, we must inform the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EEA of any planned substantial changes to our devices that could affect compliance with the Essential Requirements or the devices' intended purpose. The Notified Body will then assess the changes and verify whether they affect the products' conformity with the Essential Requirements or the conditions for the use of the devices. If the assessment is favorable, the Notified Body will issue a new CE Certificate of Conformity or an addendum to the existing CE Certificate of Conformity attesting compliance with the Essential Requirements. If it is not, we may not be able to continue to market and sell the product in the EEA.

On September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework for medical devices in the EU. These proposals provide for a revision of the current regulatory framework for medical devices in the EU to strengthen patient safety, transparency and product traceability. The proposals, for instance, include reinforced rules governing clinical evaluation throughout the life of the device, improved traceability of devices in the supply chain, including a phased and risk-based introduction of unique device identification, or UDI, improved market surveillance and vigilance, as well as better co-ordination between national regulators, increased powers for Notified Bodies to undertake unannounced inspections and strengthened supervision of Notified Bodies by member states. The European Commission's proposals may undergo significant amendments as they are reviewed by the European Council and European Parliament as part of the EU legislative process. If and when adopted, the proposed new legislation may prevent or delay the EU approval or clearance of our products under development or may impact our ability to modify our currently EU approved or cleared products on a timely basis and impose additional costs relating to clinical evaluation, vigilance and product traceability.

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Marketing and sales considerations in the EU

In the EU, 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. 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.

Product vigilance and post-approval monitoring in the EU

Additionally, all manufacturers placing medical devices into 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, manufacturers must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant authorities of the EU countries, and 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. See "Risk Factors Risks related to regulatory approval 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."

Third-party reimbursement

In the United States and most other major joint implant markets, third-party payors, including government health programs, commercial health insurers and managed care organizations, reimburse hospitals and other medical facilities an aggregate amount for all elements of a joint replacement procedure, including operating room time, patient care and the joint replacement product. As a result, our products generally are not reimbursed separately, but instead are subject to the limits imposed by third-party payors on the coverage and reimbursement of procedures that utilize our products.

Sales of our products will depend, in part, on the extent to which the costs of such procedures involving the use of our products cleared by the FDA and approved by other government authorities will be covered by third-party payors, including government health programs in the United States, such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a particular procedure may be separate from the process for setting the price or reimbursement rate that the payor will pay for the procedure once coverage is approved. Third party payors may limit coverage to particular procedures on an approved list, or formulary, which might not include all of the approved procedures involving the use of our products for a particular indication.

In the EU, pricing and reimbursement schemes vary widely from country to country. In many foreign markets, pricing of medical devices is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to limit payments by governmental payors for medical devices, and the procedures in which medical devices are used. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

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Healthcare laws and regulations

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and selection of medical devices for patients. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare 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 either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- 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 false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under the Health Care Reform Law will require manufacturers of devices, drugs and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

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.

Employees

As of May 31, 2015, we had 353 full-time employees, 87 of whom were engaged in sales and marketing, 33 in research and development, 158 in manufacturing and service, 40 in regulatory, clinical affairs and quality activities and 35 in general administrative and accounting activities. None of our employees are covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

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Facilities

Our principal facilities consist of office space and manufacturing facilities in Bedford, Burlington and Wilmington, Massachusetts. We occupy approximately 90,000 square feet of office and manufacturing space in Bedford, Massachusetts under a lease that expires in April 2017. We occupy approximately 29,000 square feet of manufacturing space in Burlington, Massachusetts under a lease that expires in July 2015. We occupy approximately 41,000 square feet of manufacturing space in Wilmington, Massachusetts under a lease that expires in April 2021. We do not intend to renew our lease for the facility in Burlington, Massachusetts when it expires in July 2015, although we expect to remain in the facility through August 2015. We are transferring our activities at our Burlington, Massachusetts facility to our facility in Wilmington, Massachusetts.

Legal proceedings

The manufacture and sale of joint replacement products is subject to routine risk of product liability and patent infringement claims. We recently settled a lawsuit against Wright Medical and MicroPort for infringement of four of our patents relating to patient-specific instrumentation. See " Intellectual Property Patent litigation." We currently are not a party to any other material legal proceedings.

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MANAGEMENT

The following table sets forth the name, age and positions of each of our executive officers, key employees and directors as of June 15, 2015 and the composition of the committees of our board of directors listed below as of the effectiveness of the registration statement of which this prospectus forms a part.

Name	Age	Position(s)
Executive Officers		
Philipp Lang, M.D.(4)	52	President and Chief Executive Officer and Director
Paul Weiner	51	Chief Financial Officer
Daniel Steines, M.D., M.S.	46	Chief Technology Officer
David Cerveny	48	Chief Legal Officer and General Counsel
Robert Law III	51	Senior Vice President, Sales
Matthew Scott	40	Senior Vice President, Operations
Key Employees		
Amita Shah, M.S.	61	Senior Vice President, Regulatory and Quality Affairs
John Slamin	61	Senior Vice President, Knee Implant Engineering
Adam Hayden	42	Senior Vice President, Marketing
Ricky Paxton	60	Vice President, Sales, Eastern U.S. and Area Vice President, Southeast U.S.
Non-Employee Directors		
Kenneth Fallon III(3)	76	Director and Chairman of the Board of Directors
Bradley Langdale(1)(2)	51	Director
Colm Lanigan(2)	49	Director
Richard Meelia	66	Director
Michael Milligan(1)(3)	51	Director
Frank Mühlenbeck, Ph.D.(3)	44	Director
Aditya Puri(2)(4)	44	Director
Laurent Souviron(1)	48	Director

(1) Member of audit committee.

(2) Member of compensation committee.

(3) Member of the nominating and corporate governance committee.

(4) Member of the Asia strategy committee.

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The following is a brief biography of each of our executive officers, key employees and non-employee directors:

Executive officers

Philipp Lang, M.D. is our founder and has served on our board of directors since March 2004, including as Chairman of our board of directors from March 2004 to February 2015. He has also served as our Chief Executive Officer since January 2008. He was also the founder of ImaTx, Inc., one of our wholly-owned subsidiaries, which focuses on osteoporosis screening. He previously held positions as the director of the musculoskeletal radiology unit at Brigham and Women's Hospital and Associate Professor at Harvard Medical School from September 2001 to September 2008 and as Distinguished Weissman Chair from May 2006 to September 2008. Dr. Lang has an M.B.A. from the University of California, Los Angeles Anderson School of Management and an M.D. from Albert-Ludwigs University, Freiburg School of Medicine in Germany. Dr. Lang has provided strategic leadership as an inventor of technology underlying more than 300 patents and patent applications in the United States and abroad. We believe that Dr. Lang is uniquely qualified to serve on our board of directors due to his institutional knowledge of our company as its founder as well as his extensive experience in the medical device industry.

Paul Weiner has served as our Chief Financial Officer since April 2014. Prior to joining us, Mr. Weiner spent 18 years at Palomar Medical Technologies, Inc., or Palomar, a company engaged in research, development, manufacturing and sales of medical laser devices for aesthetic treatments, prior to its acquisition by Cynosure, Inc. He served in a number of roles at Palomar, including corporate controller, vice president of finance and, finally, chief financial officer, a position he held for 11 years. Prior to Palomar, Mr. Weiner was the chief financial officer at Hygenetics Environmental Services, Inc., an environmental consulting company, and worked in public accounting for Ernst & Young and Wolf & Company. Mr. Weiner is a Certified Public Accountant and has a B.S. in Accounting from Bryant University.

Daniel Steines, M.D., M.S. has served as our Chief Technology Officer since June 2014. From July 2004 to June 2014, he was our Senior Vice President of Research & Development. Prior to joining us, he served as the Senior Vice President of Research & Development for ImaTx, Inc., one of our wholly-owned subsidiaries, from September 2001 to July 2004, where he was responsible for the development of image analysis applications for the diagnosis of osteoarthritis and osteoporosis. Prior to that, he held research positions at Stanford University and The Charité, Universitätsmedizin in Berlin, working in the areas of new imaging techniques to assess osteoarthritis and articular cartilage as well as novel medical video applications. Dr. Steines has an M.S. in computer science from the Technical University and an M.D. from the Technical University of Aachen.

David Cerveny has served as our Chief Legal Officer and General Counsel since October 2008. Prior to joining us, Mr. Cerveny was the chief intellectual property counsel for Palomar, where he managed an extensive patent portfolio, active patent litigation and licensing strategy. He also was previously a partner at Hale and Dorr LLP, now Wilmer Cutler Pickering Hale and Dorr LLP, and an associate at Proskauer Rose LLP. Prior to law school, Mr. Cerveny worked as a systems engineer developing flight control systems for McDonnell Douglas Corporation, an aerospace manufacturing corporation now part of The Boeing Company. Mr. Cerveny has a B.S. in biomedical engineering from Marquette University and a J.D. from Boston College Law School.

Robert Law III has served as our Senior Vice President, Sales since January 2012. From February 2008 to January 2012, he served as our Vice President of Sales, U.S. Western Region, and since April 2007, has served as a member of our sales management team. Before joining us, Mr. Law was a partner in CORE Outpatient Services, a medical device distributor. Mr. Law began his medical device career at SportsWorld Orthopedics, Inc., a medical device and post-surgical rehabilitation product distributor, where he held various senior executive roles including vice

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president of sales. Mr. Law has a B.S. with an emphasis in Kinesiology from Kansas State University.

Matthew Scott has served as our Senior Vice President, Operations since April 2013. Prior to joining us, Mr. Scott was the director of operations at Zimmer Dental Inc., a medical device company specializing in dental products, from April 2010 to April 2013, where he led all operations functions, including global supply chain management, production management and manufacturing engineering. Prior to that, Mr. Scott was director of global operations at Zimmer Holdings, Inc., Zimmer Dental's parent company, from March 2006 to April 2010 where he was responsible for site startup and manufacturing transfers and global continuous improvement programs. Mr. Scott had over 11 years of manufacturing and engineering management experience at Zimmer. Mr. Scott began his career with General Electric Company as a member of the technical leadership program. Mr. Scott has a B.S. in Mechanical Engineering Technology from Purdue University.

Key employees

Adam Hayden has served as our Senior Vice President, Marketing since April 2015, with responsibility for our international sales, product management, corporate communications, meetings and events and medical education outreach. From June 2013 to April 2015, he served as our Vice President, Marketing. From May 2012 to May 2013, he led our knee product management efforts. Prior to joining us, Mr. Hayden held various senior marketing positions from May 2007 to December 2011 at Smith & Nephew, a medical device company specializing in joint replacement products, including director of marketing responsible for global biomaterials franchise. From May 2002 to May 2007, he also held senior marketing positions at Johnson & Johnson's Orthopaedic Division, now DePuy Orthopedics, Inc., or Depuy. Prior to his career in orthopedics, Mr. Hayden served as a Captain in the U.S. Army. Mr. Hayden has a B.S. in Mechanical Engineering from Cornell University, an M.B.A. from the University of Colorado and an M.S. in Biomedical Engineering from the University of Michigan.

Ricky Paxton has served as our Vice President, Sales, Eastern U.S. since February 2014, with responsibility for all aspects of sales management for the Eastern United States regions, and Area Vice President, Southeast U.S. since January 2013. From April 2011 to December 2012, he was a member of our Regional Sales Management team. From February 2000 to April 2011, Mr. Paxton served in various sales and sales management positions at GlaxoSmithKline plc, or GSK, a global healthcare company. Prior to GSK, Mr. Paxton served as a regional sales manager at NeuroMetrix, Inc., a medical device distributor, and a sales representative in the Patient Care Division of Procter & Gamble Co., a global manufacturer of household products. Mr. Paxton has a B.S.B.A. with a Business Law concentration from Western Carolina University.

Amita Shah, M.S. has served as our Senior Vice President, Regulatory and Quality Affairs since August 2008, with responsibility for quality assurance and regulatory affairs functions. Prior to joining us, Ms. Shah served as director of quality assurance and regulatory affairs at ESA Biosciences, Inc., a diagnostic medical device company, from January 2008 to July 2008, where she led and managed the company's quality assurance and regulatory affairs activities. Prior to that, Ms. Shah served as the director of quality affairs at Confluent Surgical Inc., a cranial and spinal sealant company. Ms. Shah also has over a decade of experience in cardiovascular devices with C.R. Bard, Inc., a medical device company, where she advanced through positions of increasing responsibility in the quality assurance and regulatory affairs functions. Ms. Shah has a B.S. in Biology and Chemistry and an M.S. in Organic Chemistry, both from Kanpur University in India, as well as a Regulatory Affairs Certification from the Regulatory Affairs Professionals Society.

John Slamin has served as our Senior Vice President, Knee Implant Engineering since October 2007, with responsibility for overseeing all product engineering and development of our knee implants. Before joining us, Mr. Slamin spent more than 30 years in research and development at

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Johnson & Johnson's Orthopaedic Division, now DePuy, where he was responsible for product development activities. Mr. Slamin is the holder of seven patents related to knee implant engineering. Mr. Slamin has an Associate Degree in Mechanical Engineering from Wentworth Institute of Technology in Boston, Massachusetts.

Non-employee directors

Kenneth Fallon III has served as a member of our board of directors since January 2005, including as Chairman of our board of directors since February 2015. Mr. Fallon retired from active employment in March 2003. From time to time between March 2004 to June 2009, Mr. Fallon served as an advisor to Kairos Partners, an investment firm. Mr. Fallon retired as the chairman of the board of Axya Medical, Inc., a medical device company, in March 2003. Prior to that, Mr. Fallon also served as the chief executive officer of Axya Medical, Inc.; as president of the surgical business at Haemonetics Corporation, a manufacturer of blood processing technology; as chief executive officer and chairman of the board of UltraCision, Inc., a developer and manufacturer of ultrasonically powered surgical instruments; as president and chief executive officer of American Surgical Technologies Corporation, a company that manufactures laparoscopic viewing systems; as president, U.S. operations of Zimmer, Inc., a joint replacement company and then a subsidiary of Bristol-Myers Squibb Company; as president of Zimmer's Orthopaedic Implant Division and as its vice president of marketing and positions of significant responsibility with the Codman and Orthopaedic Divisions of Johnson & Johnson, a global healthcare company. Mr. Fallon also served as a member of the board of directors of Osteotech, Inc.,a company that produces bone graft materials for spinal procedures, between 1995 and 2010, including serving as chairman from April 2005 to August 2010, until it was acquired by Medtronic, Inc. Mr. Fallon has a B.B.A. degree in marketing from the University of Massachusetts and an M.B.A. from Northeastern University. We believe that Mr. Fallon is qualified to serve on our board of directors due to his experience in the medical device industry, particularly his experience serving as the chief executive officer and a member of the board of directors of several medical device companies.

Bradley Langdale has served as a member of our board of directors since May 2008. From February 1996 until his retirement from active employment in December 2007, Mr. Langdale served in various roles at Masimo Corporation, a noninvasive monitoring technology company, including executive vice president, chief financial officer and executive vice president, chief marketing officer. In addition, Mr. Langdale previously served as director of finance for CareLine, Inc., an emergency medical services provider; manager of financial forecasting for Sunrise Company, a private real estate development company; and as a senior accountant for Price Waterhouse & Company LLP (now PricewaterhouseCoopers LLP), a global professional services organization. Mr. Langdale is a Certified Public Accountant and has a B.A. in Economics/Business from the University of California, Los Angeles. We believe that Mr. Langdale is qualified to serve on our board of directors due to his extensive management, accounting and business experience.

Colm Lanigan has served as a member of our board of directors since July 2013. Since October 2012, Mr. Lanigan has been a senior investment professional at the Abu Dhabi Investment Authority, a sovereign wealth fund and parent company of Procific. From February 2006 to July 2011, Mr. Lanigan served as the chief executive officer at Tara Technologies Corporation, a manufacturing company in the semiconductor, aerospace, energy and medical markets, which was subsequently acquired by EnPro Industries, Inc. His prior experience includes service as Managing Director at Caxton-Iseman Capital, a private equity fund, and as a managing partner at Tara Capital Management, a hedge fund sponsor. Mr. Lanigan has a B.Sc. from the University of Toronto and a J.D./L.L.B. from the University of Toronto Law School. We believe that Mr. Lanigan is qualified to serve on our board of directors due to his extensive investment and capital raising experience across multiple industries.

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Richard Meelia has served as a member of our board of directors since June 2015. Since July 2011, Mr. Meelia has served as a principal of Meelia Ventures, LLC, a private equity firm focused on early stage healthcare companies. From July 2007 to July 2011, Mr. Meelia served as president and chief executive officer of Covidien plc, a global healthcare products company, which was formerly known as Tyco Healthcare prior to its separation from Tyco International, a healthcare security company, in June 2007. From January 1995 through its separation from Tyco International in June 2007, Mr. Meelia served as the president of Tyco Healthcare. From January 1991 to January 1995, Mr. Meelia served as the group president of Kendall Healthcare Products Company, a medical products manufacturer and the foundation of the Tyco Healthcare business. Since July 2011, Mr. Meelia has served as chairman of the board of directors of Haemonetics Corporation, a global provider of blood and plasma supplies and services. He also currently serves as chairman of the board of Apollo Endosurgery Inc., a private company focused on the development of devices that advance therapeutic endoscopy, and as a member of several charitable boards, including Tufts Medical Center and St. Anselm College. In addition, Mr. Meelia served as chairman of the board of directors of Covidien plc from October 2008 to March 2012. Mr. Meelia has a B.A. from Saint Anselm College and an M.B.A. from Boston College. We believe Mr. Meelia is qualified to serve on our board of directors due to his years of leadership experience in the global healthcare industry.

Michael Milligan has served as a member of our board of directors since November 2011. Since October 2002, Mr. Milligan has served as president and chief executive officer at Axel Johnson Inc., a private industrial and investment company. Prior to joining Axel Johnson Inc., Mr. Milligan spent 17 years as a partner and member of the board of directors of Monitor Group, a global consulting and merchant banking firm. In addition, Mr. Milligan is chairman of the board of directors of Sprague Resources Limited Partners, a supplier of energy and materials handling services in the Northeast United States and is a member of the board of directors of Cadence Inc., a supplier of advanced products, technologies and services to medical, life science, automotive, and industrial companies, Decisyon Inc., an enterprise software company, Kinetico Incorporated, a residential and commercial water treatment systems provider, Parkson Corporation, a provider of engineered solutions for municipal and industrial water treatment, and Walk2Campus Holdings, LLC, a real estate investment company providing student housing in proximity to public universities. Mr. Milligan has an A.B. from Bowdoin College and an M.B.A. from Harvard University. We believe that Mr. Milligan is qualified to serve on our board of directors due to his extensive business and investment experience across a broad range of disciplines and industry sectors.

Frank Mühlenbeck, Ph.D., has served as a member of our board of directors since May 2009. Since November 2006, Dr. Mühlenbeck has served as a partner at aeris CAPITAL, a private investment office advising high-net-worth individuals. At aeris he heads up a team responsible for private and public equity investments in life sciences companies. In this capacity, Dr. Mühlenbeck serves on different boards of life science companies in Europe and the United States, including Affimed N.V., an antibody-drug development company, Solstice Biologics Inc., a ribonucleic acid interference therapeutics company, and Curetis AG, a molecular diagnostics company. Dr. Mühlenbeck earned a Ph.D. in cell biology and immunology from Stuttgart University. We believe that Mr. Mühlenbeck is qualified to serve on our board of directors due to his diverse business background with life sciences companies and wealth management.

Aditya Puri has served as a member of our board of directors since December 2011. Mr. Puri has served as an investments director at Xeraya Capital, which is responsible for life sciences investments for Khazanah Nasional Berhad, the Malaysian government's strategic investment fund, since October 2012. Previously, he was a director in Khazanah Nasional's Life Sciences group since November 2011. Prior to that, Mr. Puri consulted part-time in the greater Boston area for various healthcare and cleantech startups affiliated with Harvard University and Massachusetts Institute of Technology, or MIT, from August 2009 to September 2011. Previously, Mr. Puri also served as managing director of global development at Salary.com, a skills management software company,

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and as a vice president of the Yankee Group, an information technology research and advisory company. Mr. Puri serves on several boards of directors of private companies in the investment and healthcare fields, including Viewray Incorporated, a medical device company. Mr. Puri has a B.S. from the University of Southern Maine and an M.B.A. from the MIT Sloan School of Management. We believe Mr. Puri is qualified to serve on our board of directors because of his extensive experience in life sciences and other areas of growth investment.

Laurent Souviron has served as a member of our board of directors since November 2011. Since September 2009, Mr. Souviron has served as managing director of AGC Equity Partners, an alternative investment firm. Prior to joining AGC Equity Partners, Mr. Souviron was a managing director at Morgan Stanley, a financial services corporation, in London and started his career with Morgan Stanley in New York. He also previously served as a managing director with the SUN Group, a private equity company. Mr. Souviron has a B.S. in Operations Research and an M.B.A. in Finance from Columbia University. We believe Mr. Souviron is qualified to serve on our board of directors because of his extensive international finance and capital raising experience.

Board composition

Our board of directors currently consists of nine members. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

Our restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering provide that the authorized number of directors may be changed only by resolution of the board of directors. Our restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

In accordance with the terms of our restated certificate of incorporation and bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows

the class I directors will be Richard Meelia, Frank Mühlenbeck and Laurent Souviron, and their term will expire at the annual meeting of stockholders to be held in 2016;

the class II directors will be Colm Lanigan, Michael Milligan and Aditya Puri, and their term will expire at the annual meeting of stockholders to be held in 2017; and

the class III directors will be Kenneth Fallon III, Philipp Lang and Bradley Langdale, and their term will expire at the annual meeting of stockholders to be held in 2018.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

We have entered into a Sponsor Designee Recommendation Agreement with Procific, or the Procific Agreement, which will become effective upon the closing of this offering. The Procific

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Agreement provides that, in the event that Colm Lanigan should cease to serve as a member of our board of directors prior to the expiration of his term upon the commencement of our 2017 annual meeting of stockholders, prior to filling such vacancy, Procific will have the opportunity to recommend to our nominating and corporate governance committee an individual to fill such vacancy and to serve for the balance of Mr. Lanigan's incompleted term. Procific will no longer have rights under the Procific Agreement at such time as Procific and its affiliates no longer beneficially own at least 5% of the outstanding shares of our common stock. In addition, the Procific Agreement will terminate upon the earlier to occur of (a) a change of control, as defined in the Procific Agreement, (b) Procific's delivery of written notice to us requesting termination and (c) the commencement of our 2017 annual meeting of stockholders.

The classification of our board of directors may have the effect of delaying or preventing changes in our control or management. See "Description of Capital Stock Anti-takeover effects of Delaware law and our charter and bylaws."

Director Independence

Rule 5605 of the NASDAQ Listing Rules requires a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the NASDAQ Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Under Rule 5605(a)(2) of the NASDAQ Listing Rules, a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries. In addition, in affirmatively determining the independence of any director who will serve on a company's compensation committee, Rule 10C-1 under the Exchange Act requires that a company's board of directors consider all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting, advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In May 2015 our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Dr. Lang, is an "independent director" as defined under Rule 5605(a)(2) of the NASDAQ Listing Rules. Our board of directors also determined that Bradley Langdale, Michael Milligan and Laurent Souviron, who will comprise our audit committee following this offering, and Bradley Langdale, Colm Lanigan and Aditya Puri, who will comprise our compensation committee following this offering, satisfy the independence standards for such committees established by the SEC and the NASDAQ Listing Rules, as applicable. In making such determinations, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances our board of directors

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deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

There are no family relationships among any of our directors or executive officers.

Board committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will, upon the effectiveness of the registration statement of which this prospectus forms a part, operate under a charter that has been approved by our board of directors. Our board also has established an Asia strategy committee which will remain in existence until the second anniversary of the closing of the offering contemplated by the registration statement of which this prospectus forms a part. The composition of each committee will be effective upon effectiveness of the registration statement of which this prospectus forms a part. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Our board of directors may establish other committees to facilitate the management of our business.

Audit committee

The members of our audit committee will be Bradley Langdale, Michael Milligan and Laurent Souviron. Mr. Langdale will be the chair of the audit committee. Our board of directors has determined that each of these directors is independent within the meaning of Rule 10A-3 under the Exchange Act. In addition, our board of directors has determined that Mr. Langdale qualifies as an audit committee financial expert within the meaning of SEC regulations and the NASDAQ Listing Rules. In making this determination, our board has considered the formal education and nature and scope of his previous experience, coupled with past and present service on various audit committees. Our audit committee assists our board of directors in its oversight of our accounting and financial reporting process and the audits of our financial statements. Our audit committee's responsibilities will include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and our independent registered public accounting firm our quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our internal audit function, if any;
- discussing our risk management policies;
- establishing procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our internal auditing staff, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related-person transactions; and
- preparing the audit committee report required by SEC rules.

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All audit services to be provided to us and all non-audit services, other than de minimis non-audit services, to be provided to us by our registered public accounting firm must be approved in advance by our audit committee.

Compensation committee

The members of our compensation committee will be Bradley Langdale, Colm Lanigan and Aditya Puri. Mr. Langdale will be the chair of the compensation committee. Our compensation committee assists our board of directors in the discharge of its responsibilities relating to the compensation of our executive officers. The compensation committee's responsibilities will include:

- reviewing and approving, or recommending for approval by our board of directors, our Chief Executive Officer's compensation as well as the compensation of our other executive officers;
- overseeing the evaluation of our Chief Executive Officer;
- reviewing and making recommendations to our board of directors with respect to our incentive-compensation and equity-based compensation plans;
- overseeing and administering our equity-based plans;
- reviewing and making recommendations to our board with respect to director compensation;
- reviewing and discussing with management our "Compensation Discussion and Analysis" disclosure to the extent such disclosure is required by SEC rules; and
- preparing the compensation committee report required by SEC rules.

Nominating and corporate governance committee

The members of our nominating and corporate governance committee will be Kenneth Fallon III, Michael Milligan and Frank Mühlenbeck. Mr. Fallon will be the chair of the nominating and corporate governance committee. The nominating and corporate governance committee's responsibilities will include:

- identifying individuals qualified to become members of our board;
- recommending to our board the persons to be nominated for election as directors and to each of our board's committees;
- reviewing and making recommendations to our board of directors with respect to management succession planning;
- developing and recommending to our board corporate governance principles; and
- overseeing a periodic evaluation of our board.

Asia strategy committee

Prior to the effectiveness of the registration statement of which this prospectus forms a part, the members of our Asia strategy committee were Philipp Lang, Kenneth Fallon III, Bradley Langdale and Aditya Puri. Dr. Lang was the chair of the Asia Strategy Committee. Effective upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our Asia strategy committee will be Mr. Puri and Dr. Lang. Mr. Puri will be chair of the Asia strategy committee.

The Asia strategy committee will have the authority to oversee our business development activities in Asia. It will remain in existence until the second anniversary of the closing of the offering contemplated by the registration statement of which this prospectus forms a part.

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Compensation committee interlocks and insider participation

None of our executive officers serves, or in the past has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of our board of directors or our compensation committee. None of the members of our compensation committee is an officer or employee of our company, nor have they ever been an officer or employee of our company.

Code of business conduct and ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We intend to post on our website, www.conformis.com, a current copy of the code and all disclosures that are required by law or NASDAQ stock market listing standards concerning any amendments to, or waivers from, any provision of the code.

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EXECUTIVE COMPENSATION

This section discusses the material elements of compensation awarded to, earned by or paid to our named executive officers in 2014. Our named executive officers for 2014 were Philipp Lang, who served as our President and Chief Executive Officer, Paul Weiner, who served as our Chief Financial Officer, and Daniel Steines, who served as our Chief Technology Officer. This section also includes qualitative information regarding the manner and context in which compensation is awarded to and earned by our named executive officers and is intended to place in perspective the data presented in the following tables and the corresponding narrative.

Summary compensation table

The following table sets forth information regarding compensation awarded to, paid to or earned by our named executive officers during 2014.

Name	Year	Salary ($)	Option awards ($)(1)	All other compensation ($)	Total ($)
Philipp Lang, M.D. *President and Chief Executive Officer*	2014	365,000	720,539	583,528(2)	1,669,067
Paul Weiner *Chief Financial Officer*	2014	231,923(3)	1,145,636	3,250(4)	1,380,809
Daniel Steines, M.D., M.S. *Chief Technology Officer*	2014	230,063	393,021	4,808(4)	627,892

(1) The amounts reported in the "Option Awards" column reflect the aggregate fair value of share-based compensation awarded during the year computed in accordance with the provisions of FASB Accounting Standard Codification Topic 718. See Note L to our audited financial statements appearing at the end of this prospectus regarding assumptions underlying the valuation of equity awards.

(2) Such amount consists of $578,810 that Dr. Lang was entitled to receive for 2014 pursuant to a revenue share agreement, which is discussed in "Certain Relationships and Related-Persons Transactions Revenue share agreement with Dr. Lang", and $4,718 that we contributed to our 401(k) plan in respect of Dr. Lang.

(3) Mr. Weiner joined the Company on March 24, 2014 and has an annualized base salary of $300,000, which was prorated in 2014.

(4) Includes the amount we contributed to our 401(k) plan in respect of the applicable named executive officer.

Narrative disclosure to summary compensation table

We review compensation annually for all employees, including our executives. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to our company. We do not target a specific competitive position or a specific mix of compensation among base salary, bonus or long-term incentives.

Our board of directors has historically determined our executives' compensation. Our compensation committee typically reviews and discusses management's proposed compensation

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with our Chief Executive Officer for all executives other than our Chief Executive Officer. Based on those discussions and its discretion, the compensation committee then recommends to our board of directors the compensation for each executive officer, other than our Chief Executive Officer, including equity based awards. The compensation committee has the authority to approve the cash compensation of our executive officers, other than our Chief Executive Officer and President, but has historically made recommendations to our board of directors regarding such compensation. Our board of directors, without members of management present, discusses the compensation committee's recommendations and ultimately approves the compensation of our executive officers, including our Chief Executive Officer. In the fourth quarter of 2013, we engaged Frederic W. Cook & Co. as our independent compensation consultant to review our executive compensation peer group and program design and assess our executives' compensation relative to comparable companies.

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. None of our named executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary. In 2014, we paid base salaries of $365,000 to Dr. Lang, $231,923 to Mr. Weiner and $230,063 to Dr. Steines. Mr. Weiner's employment began on March 24, 2014 and, as a result, the amount shown in the "Salary" column of the Summary Compensation Table reflects payments made to him from the period between March 24, 2014 and December 31, 2014. For 2014, Mr. Weiner's annualized base salary was $300,000.

We have not historically had a formal performance-based bonus plan. Our board of directors has, in its discretion, awarded cash bonuses and granted equity awards in the form of stock options as bonuses to our executive officers from time to time in the past, and may award cash bonuses and grant equity awards as bonuses to our executive officers in the future. See "Executive Compensation Stock option and other compensation plans 2015 annual cash bonus and equity grant plan" for a description of our cash and equity bonus plan for 2015.

In connection with his appointment as Chief Financial Officer, the board of directors originally approved a stock option grant to Mr. Weiner at an exercise price per share above the then-current fair market value per share of common stock. This stock option award was subsequently amended in September 2014, to provide for an exercise price of $8.96 per share, which was the then-current fair market value of our common stock based on our per-share estimated valuation as of such date.

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Outstanding equity awards at year end

The following table sets forth information regarding outstanding stock options held by our named executive officers as of December 31, 2014.

	Option awards			
Name	**Number of securities underlying unexercised options (#) exercisable**	**Number of securities underlying unexercised options (#) unexercisable**	**Option exercise price ($)**	**Option expiration date**
Philipp Lang, M.D.	13,747	68,753(1)	10.96	8/3/2024
President and Chief	13,747	68,753(1)	8.96	8/3/2024
Executive Officer	7,613		5.50	3/26/2022
		187,500(2)	5.50	3/27/2022
	246,008		5.26	9/26/2021