ConforMIS Inc
Form S-1
May 22, 2015

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Table of Contents

As filed with the Securities and Exchange Commission on May 21, 2015.

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
Under
THE SECURITIES ACT OF 1933

ConforMIS, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**3841**	**56-2463152**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code No.)	(I.R.S. Employer Identification No.)

28 Crosby Drive
Bedford, MA 01730
(781) 345-9001
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Philipp Lang, M.D.
President and Chief Executive Officer
28 Crosby Drive
Bedford, MA 01730
(781) 345-9001
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

David Cerveny, Esq.
Chief Legal Officer & General Counsel

ConforMIS, Inc.
28 Crosby Drive
Bedford, MA 01730
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Boston, MA 02109	**San Diego, CA 92130**	**450 Lexington Avenue**
(617) 526-6000	**(858) 720-5737**	**New York, NY 10017**
		(212) 450-4000

Approximate date of commencement of proposed sale to the public:
As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), please check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Proposed maximum aggregate offering price(1)(2)**	**Amount of registration fee(3)**
Common stock, par value $0.00001 per share	$172,500,000	$20,045

(1) Estimated solely for the purpose of computing the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended.

(2) Includes the aggregate offering price of additional shares that the underwriters have the option to purchase.

(3) Calculated pursuant to Rule 457(o) based on a bona fide estimate of the maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

Subject to completion, dated May 21, 2015

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

shares

Common stock

This is an initial public offering of common stock by ConforMIS, Inc. We are selling shares of common stock. The estimated initial public offering price is between $ and $ per share.

Prior to this offering, there has been no public market for our common stock. We have applied to have our common stock listed on the NASDAQ Global 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	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to ConforMIS, before expenses	$	$

(1) We have agreed to reimburse the underwriters for certain FINRA-related expenses. See "Underwriting" beginning on page 171 of this prospectus.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 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 , 2015.

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

Wells Fargo Securities **Canaccord Genuity**

The date of this prospectus is , 2015.

Table of Contents

Table of Contents

TABLE OF CONTENTS

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.

Table of Contents

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 86 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

Table of Contents

$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. According to one study, 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 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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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 we are unable to obtain favorable reimbursement rates from third-party payors for our new products, or if reimbursement from third-party payors for our products 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.

Table of Contents

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.

Table of Contents

THE OFFERING

Common stock offered by us	shares
Common stock to be outstanding after this offering	shares
Option to purchase additional shares	The underwriters have an option for a period of 30 days to purchase up to additional shares of our common stock.
Use of proceeds	We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately $ million, assuming an initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting estimated 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 $ million. We intend to use the net proceeds of this offering as follows: approximately $ million to purchase and install capital equipment to expand our manufacturing capacity; approximately $ million to expand and support our sales and marketing efforts; and approximately $ 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.
Proposed NASDAQ Global Market symbol	"CFMS"

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

8,691,595 shares of our common stock outstanding as of April 30, 2015;

50,995,026 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;

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

Table of Contents

closing of this offering, which we refer to as the net exercise warrants, and which consist of warrants to purchase:

- 919,802 shares of our Series E-1 and E-2 preferred stock at an exercise price of $8.00 per share;
- 129,823 shares of our Series D preferred stock at an exercise price of $6.00 per share; and
- 8,333 shares of our common stock at an exercise price of $2.16 share.

assuming an initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, and we refer to the foregoing as the assumed warrant exercises; and

406,874 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:

1,368,674 shares of our common stock issuable upon the exercise of warrants outstanding as of April 30, 2015, at a weighted average exercise price of $5.05 per share other than shares issuable in connection with the assumed warrant exercises and the Series D warrant exchange;

66,964 shares of common stock issuable upon exercise of warrants to purchase common stock, at an exercise price of $4.48 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;

11,264,036 shares of our common stock issuable upon the exercise of stock options outstanding as of April 30, 2015, at a weighted average exercise price of $2.65 per share;

492,978 shares of our common stock available for future issuance under our 2011 stock incentive plan as of April 30, 2015; and

an additional 4,000,000 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 50,995,026 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 April 30, 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 682,665 shares of our common stock, at an exercise price of $6.00 per share, upon the closing of this offering;

Table of Contents

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 285,714 shares of our common stock at an exercise price of $3.50 per share, which we refer to as the Series C warrant exchange;

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 additional shares.

Table of Contents

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)	$ (5.99)	$ (5.39)	$ (1.52)	$ (1.66)
Weighted-average number of common shares used in net loss per share applicable to common stockholders basic and diluted(1)	7,993,736	8,479,134	8,331,522	8,593,227
Pro forma net loss per share applicable to common stockholders basic and diluted (unaudited)(1)(2)		$		$

Pro forma weighted average number of common shares outstanding basic and diluted (unaudited)(1)(2)	$	$

Table of Contents

(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	$ 22,939	$
Working capital	31,065	31,065	
Total assets	60,705	60,705	
Long-term debt, including current portion	10,560	10,560	
Total stockholders' equity	36,781	36,781	

(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 automatic conversion of all outstanding shares of our preferred stock into 50,985,652 shares of common stock, (b) the assumed warrant exercises and (c) the Series D warrant exchange.

(3) The pro forma as adjusted balance sheet data give further effect to our issuance and sale of shares of common stock in this offering (assuming no exercise by the underwriters of their option to purchase additional shares) at an assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital and total stockholders' deficit by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated 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 $2.16 to $8.00 per 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 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 $ million.

Table of Contents

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.

Table of Contents

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. 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;
- 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;

Table of Contents

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.

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

Table of Contents

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
- 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

15

Table of Contents

products. In addition, based on their favorable attributes, we expect our products to be offered at higher price points than some competitive products, and our pricing decisions may make our products less competitive.

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

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

increase sales of our products;

negotiate more favorable prices for the materials we use to manufacture our products;

negotiate more favorable prices for the manufacture of certain components of our products that are manufactured for us by third parties;

deploy new versions of our software that reduce the costs associated with the design of our products; and

expand our internal manufacturing capabilities to manufacture certain components of our products at a lower unit cost than vendors we currently use.

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

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

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

We believe orthopedic surgeons will not widely adopt our products unless they determine, based on experience, clinical data and published peer-reviewed journal articles, that our products and the techniques to implant them provide benefits to patients and are attractive alternatives to our

Table of Contents

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 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 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 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

Table of Contents

the choice of implant product can lead to patient dissatisfaction. Furthermore, based on their prior experience using non-customized, off-the-shelf implant products, surgeons may be accustomed to making modifications to the implant components during a procedure. Because our products are already individually-made to fit the unique anatomy of each patient, modifications made to the implant components or the process of fitting the implant during the surgical procedure are not recommended and may result in negative surgical outcomes. If patients do not have a good outcome following procedures conducted using our products, surgeons' views of our products may be negatively impacted.

The first step in the process for a patient to receive one of our joint replacement products involves a CT scan of the patient's affected joint and one or two CT images of other biomechanically relevant joints. CT scans involve the use of radiation to image the bone and other tissue in the scanned joint. Surgeons may be reluctant to recommend, and patients may be reluctant to undertake, a procedure that involves this imaging modality as a result of the actual or perceived risks of exposure to radiation as part of the CT scan. The use of an off-the-shelf joint replacement product generally does not require a CT scan. As a result, surgeons and patients may view the alternative joint replacement approaches that do not require a CT scan as more attractive. Competitors may promote their products on this basis, and as a result, our sales, revenue and profitability may be adversely affected.

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

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

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

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

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

Table of Contents

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 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 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.

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

Table of Contents

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.

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.

Table of Contents

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.

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.

Table of Contents

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

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

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

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

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

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

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

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

Table of Contents

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.

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.

Table of Contents

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 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.

Table of Contents

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, 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.

Table of Contents

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 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.

Table of Contents

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 July 2015, when the lease for our Burlington facility expires. 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;

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.

Table of Contents

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.

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

Table of Contents

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.

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

Table of Contents

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 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.

Table of Contents

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 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.

Table of Contents

Risks related to managing our future growth

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

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

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

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

If we lose one or more of our executive officers, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous medical device companies for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

Table of Contents

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 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.

Table of Contents

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 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.

Table of Contents

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

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

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

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

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

Our commercial success depends in part on not infringing the patents or violating the other proprietary rights of others and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or products, including interference or derivation proceedings before the U.S. Patent and Trademark Office. Significant litigation regarding patent rights occurs in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or

Table of Contents

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.

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

Table of Contents

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.

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

Table of Contents

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 asceptic loosening, which is a condition caused by wear debris generated by the implant. We or our suppliers could suffer breaches to our sterilization procedures, which could cause contamination of the affected components and products we market and ultimately could cause infections in patients. Moreover, patients may be dissatisfied with the results of joint replacement surgery even if there is no medical complication. Furthermore, if orthopedic surgeons are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients.

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

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

- decreased demand for our products;
- injury to our reputation;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients, especially in the event of a class action lawsuit;
- product recalls;

Table of Contents

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;

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.

Table of Contents

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 under Section 510(k) of the FDCA or an approval of a premarket approval, or PMA, application 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 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;

Table of Contents

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 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

Table of Contents

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 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

Table of Contents

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 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.

Table of Contents

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;

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;

Table of Contents

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 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

Table of Contents

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 has inspected our Bedford, Massachusetts facility and quality system, most recently in February 2013. Our Wilmington, Massachusetts facility will require registration with, but not inspection by, the FDA before we can commence selling products manufactured at the facility. 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.

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.

Table of Contents

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 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.