ConforMIS Inc
Form 10-K
March 24, 2016

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

OR

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

For the transition period from to

Commission file number: 001-37474

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

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

(781) 345-9001
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	Name of Exchange on Which Registered
Common Stock, $0.00001 par value	NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act:
None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No þ

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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	¨	Accelerated filer	¨
Non-accelerated filer	þ (Do not check if a smaller reporting company)	Smaller reporting company	¨

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

As of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, there was no established public market for the registrant's common stock, and therefore, the registrant cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date. The registrant's common stock began trading on the NASDAQ Global Market on July 1, 2015.

As of February 29, 2016, the registrant had 41,569,337 shares of Common Stock, $0.00001 par value per share, outstanding.

Portions of the registrant's definitive proxy statement for its 2016 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2015, are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K.

ConforMIS, Inc.

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PART I

Forward-Looking Statements

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

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

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

- our estimates regarding the potential market opportunity and timing of estimated commercialization for our current and future products, including our iTotal CR, our iTotal PS and, if we receive required marketing clearances or approvals, our iTotal Hip;
- our expectations regarding our sales, expenses, gross margins and other results of operations;
- our strategies for growth and sources of new sales;
- maintaining and expanding our customer base and our relationships with our independent sales representatives and distributors;
- our current and future products and plans to promote them;
- anticipated trends and challenges in our business and in the markets in which we operate;
- the implementation of our business model, strategic plans for our business, products, product candidates and technology;
- the future availability of raw materials used to manufacture, and finished components for, our products from third-party suppliers, including single source suppliers;
- product liability claims;
- patent infringement claims;
- the impact of our voluntary recall initiated in August 2015 on our business operations, financial results and customer relations;
- our ability to retain and hire necessary employees and to staff our operations appropriately;
- our ability to compete in our industry and with innovations by our competitors;
- potential reductions in reimbursement levels by third-party payors and cost containment efforts of accountable care organizations;
- our ability to protect proprietary technology and other intellectual property and potential claims against us for infringement of the intellectual property rights of third parties;
- potential challenges relating to changes in and compliance with governmental laws and regulations affecting our U.S. and international businesses, including regulations of the U.S. Food and Drug Administration and foreign government regulators, such as more stringent requirements for regulatory clearance of our products;
- the impact of federal legislation to reform the United States healthcare system and the reimposition of the 2.3 percent medical device excise tax if and when the current moratorium is lifted;
- the anticipated adequacy of our capital resources to meet the needs of our business; and

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

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into. You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K and our other filings with the SEC completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

ITEM 1. BUSINESS

Overview

We are a medical technology company that uses our proprietary iFit Image-to-Implant technology platform to develop, manufacture and sell joint replacement implants that are individually sized and shaped, which we refer to as customized, to fit each patient's unique anatomy. The worldwide market for joint replacement products is approximately $15 billion annually and growing, and we believe our iFit technology platform is applicable to all major joints in this market. We believe we are the only company offering a broad line of customized knee implants designed to restore the natural shape of a patient's knee. We have sold a total of more than 40,000 knee implants in the United States and Europe. In clinical studies, iTotal CR, our cruciate-retaining total knee replacement implant and best-selling product, demonstrated superior clinical outcomes, including better function and greater patient satisfaction compared to traditional, off-the-shelf implants. In February 2015, we initiated the limited launch of iTotal PS, our posterior-stabilized total knee replacement implant which addresses the largest segment of the knee replacement market, and we initiated the broad commercial launch of the iTotal PS in March 2016.

Our iFit technology platform comprises three key elements:

- iFit Design, our proprietary algorithms and computer software that we use to design customized implants and associated single-use, patient-specific instrumentation, which we refer to as iJigs, based on a computed tomography, or CT, scan of the patient and to prepare a surgical plan customized for the patient that we call iView.
- iFit Printing, a three-dimensional, or 3D, printing technology that we use to manufacture iJigs and are in the process of extending to manufacture certain components of our customized knee replacement implants.
- iFit Just-in-Time Delivery, our just-in-time manufacturing and delivery capabilities.

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

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

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

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

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

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

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

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

- For the surgeon. We believe that the combination of the use of our iJigs with our customized knee replacement implants enables a more accurate, reproducible and simplified surgical procedure by reducing the number of required steps and increasing the precision of the placement of the implant. Our summary of a retrospective study of 200 knee replacement surgeries published in 2014 in the peer-reviewed Journal of Arthroplasty, or the 2014 JOA Study, indicates that our iTotal CR implant was 1.8 times more likely to be in

the desired alignment range after surgery than an off-the-shelf implant. At the time this study was conducted, one of the authors of this study was a paid consultant to us.

- For the hospital. We believe that our customized knee replacement implants and iFit technology platform provide a better economic outcome for hospitals by:
  - improving patient recovery times, reducing blood loss and reducing adverse event rates at discharge;
  - reducing the costs associated with managing and sterilizing large numbers of reusable instruments; and
  - improving turnaround times with the potential for more procedures to be completed within the same amount of time and for the hospital to generate additional revenue.

As of February 29, 2016, we own or exclusively in-license a total of approximately 500 issued patents and pending patent applications that cover customized implants and patient-specific instrumentation, or PSI, for all major joints and other elements of our iFit technology platform. Our intellectual property portfolio includes 131 issued United States patents, 64 patents issued in countries outside the United States, and 313 patent applications worldwide. We believe that our patent portfolio provides a significant barrier to entry. On February 29, 2016, we filed a lawsuit against Smith & Nephew, Inc., or Smith & Nephew, in the United States District Court for the District of Massachusetts Eastern Division. The lawsuit alleges that Smith & Nephew's Visionaire® patient-specific instrumentation, as well as the implants systems used in conjunction with the Visionaire instrumentation, infringe eight of our patents and requests monetary damages for willful infringement and a permanent injunction.

Our knee replacement products have been cleared by the U. S. Food and Drig Administration, or FDA, under the premarket notification process of Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, and have received certification to CE Mark. We market our products to orthopedic surgeons, hospitals, hospital networks, ambulatory surgery centers and other medical facilities, and patients. We use direct sales representatives, independent sales representatives and distributors to market and sell our products in the United States, Germany, the United Kingdom and other markets.

We introduced our iUni and iDuo partial knee replacement products in 2007 and our iTotal CR in 2011. For the year ended December 31, 2015, we generated revenue of $63 million from product sales, representing a 30% increase over the prior year.

Industry background

Market opportunity

Joint replacement for treatment of osteoarthritis

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

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

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

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patients between 45 and 64 years old has fueled recent growth in the TKA and THA markets. Based on these trends, we expect patient demand for total joint replacements will continue to increase.

Joint replacement market

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

According to the industry report U.S. Market for Large Bone and Joint Orthopedic Devices published in February 2014 by iData Research, or the iData Report, primary total knee replacement implants and partial knee replacement implants accounted for approximately 83% of the 2013 knee replacement market by revenue in the United States. The remaining 17% of the knee replacement market is for follow up procedures known as revision surgeries and patient-specific instruments. According to the iData Report, in 2013, of the primary total knee replacement market in the United States, posterior-stabilized procedures represented approximately 72% by revenue and cruciate-retaining procedures represented approximately 28% by revenue. The decision to perform a posterior-stabilized or cruciate-retaining total knee replacement is usually a matter of a surgeon's preferred surgical technique.

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

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

Knee implants

Knee replacement implants typically have four principal components:

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

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

Clinical shortcomings of off-the-shelf knee implants

Knees vary in size and shape; no two knees are the same. In a traditional knee replacement procedure, the surgeon must choose an off-the-shelf implant with a size and shape that the surgeon thinks will work best for the patient. However, off-the-shelf implants are not customized to fit an individual patient's knee, and during a knee replacement procedure, the surgeon has to fit the patient's soft tissue, bones and cartilage to the fixed dimensions of the implant through an iterative process of sizing and positioning. This typically entails removing bone and shaping the residual bone to the implant. Surgeons often have to make compromises on implant fit, rotation and alignment because the surgeons are limited by the size and shape of the implant. These compromises can cause residual pain and functional limitations after surgery, which we believe contribute to patient dissatisfaction. We reviewed a study of 1,703 patients published in 2009 in the peer-reviewed journal Clinical Orthopaedics and

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Related Research where patient satisfaction was determined by combining patients who answered very dissatisfied, dissatisfied or neutral into one group and patients who answered satisfied or very satisfied into a second group. Our summary of the study indicates that approximately one in five patients who receive an off-the-shelf implant is not satisfied with his or her total knee replacement.

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

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

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

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

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

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

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

Other challenges associated with off-the-shelf implants

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

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

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

Recent efforts to improve traditional knee replacement surgery

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

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

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

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

The ConforMIS Solution: One Patient, One Implant

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

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

iFit Image-to-Implant technology platform

Our iFit technology platform comprises three key elements:

- iFit Design, our proprietary algorithms and computer software that we use to design customized implants and associated iJigs based on a CT scan of the patient and to prepare a surgical plan customized for the patient that we call iView.

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

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

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

Our customized implant procedure

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

CT scan

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

Recreating the knee using three-dimensional modeling

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

Personalizing the implant

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

Development of patient-specific surgical plan

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

Just-in-time delivery to hospital

We deliver the patient's customized knee implant and iJigs to the hospital in advance of the surgery. We are able to deliver our products within six weeks in the United States and seven weeks internationally of the date of our receipt of an order, which includes a CT scan and an implant request form from the surgeon.

Key benefits of our customized products

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Fewer post-operative issues. We believe our customized knee implants reduce the number of post-operative issues. Our review of a retrospective study of 248 patients who had undergone a total knee replacement, as presented in an abstract and further updated by a poster presented at the the 2015 ICJR World Arthroplasty Congress, or the 2015 TKA Study, indicates that patients who received an iTotal CR had significantly lower transfusion rates ($p=0.005$) and adverse event rates at discharge ($p=0.003$) than patients who received an off-the-shelf total knee replacement implant. We provided financial support for this study. At the time this study was conducted, one of the authors of this study also was a paid consultant to us.

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

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

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

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

Shorter stays. We believe that our customized total knee replacements may shorten hospital stays. Our summary of the results of the 2015 TKA Study indicates that a statistically significantly greater percentage of patients who underwent total knee replacement were discharged in fewer than three days following surgery (p=0.037) in the iTotal CR group (42%) than in the off-the-shelf group (30%).

Fewer adverse events. Many insurers and third-party payors, including Medicare, require the hospital to bear the cost of treating infections and post-operative adverse events if they occur within 90 days following the implant procedure. If instruments are not properly prepared prior to surgery, they are a potential source of costly infections. The lower number of instruments used with our knee implants reduces the possibility of a contaminated instrument. Our summary of the results of the 2015 TKA Study indicates that use of our iTotal CR statistically significantly reduced blood transfusion rates (p=0.005) and adverse event rates at discharge (p=0.003) as compared to an off-the-shelf knee implant. Our review of unpublished research sponsored by us also leads us to believe that use of our iTotal CR is associated with lower adverse event rates during the 90-day period following surgery. The reduction in adverse events observed during the 90-day period following surgery is meaningful because hospitals may not be reimbursed for additional post-operative follow up care during this period.

Our strategy

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

- Broaden our product portfolio by launching additional customized orthopedic implants. While our initial focus has been on the knee implant market, we believe our iFit technology platform is applicable to customized implants for all major joints in the body and multiple implant subcategories within each joint. In February 2015, we initiated the limited launch of iTotal PS, our posterior-stabilized total knee replacement implant, to address the largest segment of the knee replacement market, and we initiated the broad commercial launch of iTotal PS in March 2016. In addition, we submitted an application for 510(k) clearance of iTotal Hip, our first customized hip replacement implant, with the FDA in 2015. We also may seek to apply our iFit technology platform to develop additional product opportunities in the knee and hip replacement markets and other orthopedic markets in the longer-term, including shoulder, other extremities, spine and ligament reconstruction.

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

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

- Expand our digitally driven, just-in-time manufacturing processes. We have built state of the art manufacturing processes, including proprietary software and 3D printing capabilities. We are continuing to invest in these processes as we believe they provide us important competitive advantages, including:
  - large-scale production of customized implants;
  - shorter product design and development time frames;
  - continuous improvement of our products without making obsolete a large inventory of implants and instruments, in contrast to manufacturers of off-the-shelf implants; and
  - expansion of gross margins through the ongoing vertical integration of our digital manufacturing processes.

- Enhance our patent portfolio and continue to exploit our patent position. As of February 29, 2016, we own or exclusively in-license a total of approximately 500 issued patents and pending patent applications that cover customized implants and PSI for all major joints and other elements of our iFit technology platform. On February 29, 2016, we filed a lawsuit against Smith & Nephew, Inc. (“Smith & Nephew”) in the United States District Court for the District of Massachusetts Eastern Division. The lawsuit alleges that Smith & Nephew’s Visionaire® patient-specific instrumentation, as well as the implants systems used in conjunction with the Visionaire instrumentation, infringe eight of our patents, and requests monetary damages for willful infringement and a permanent injunction.

Our products

Knee replacement products

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

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

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

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

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

The iUni is the only customized unicompartmental knee replacement product on the market for treatment of the medial or lateral compartment of the knee. The iUni is considered a bicruciate-retaining knee replacement because the surgeon retains both the ACL and PCL. We first

launched the iUni in June 2007 and launched new generations of the product in each of 2009 and 2012. The iUni includes a femoral implant, a tibial tray and a single polyethylene insert, all of which are individually made for the particular patient.

Hip replacement product candidate

iTotal Hip

We are currently developing our iTotal Hip to provide a customized total hip replacement implant. We submitted an application for 510(k) clearance of iTotal Hip with the FDA in 2015. We cannot predict if or when we will receive clearance or initiate the commercial launch of iTotal Hip. We expect that iTotal Hip will be our next product introduction after iTotal PS. We believe the introduction of iTotal Hip will provide synergies with our existing line of customized knee implants because most surgeons who perform knee replacements also perform hip replacements. Thus, we expect that iTotal Hip will complement our existing product line, customer base, sales force and distribution channels.

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

- Implant dislocation. Hip implant dislocation occurs when the head of the femoral component dislodges from the hip socket component, which is referred to as the acetabular component, or hip cup. This can result from one or more of the following:
  - an inappropriate angle between the stem and the neck of the femoral component, referred to as neck angle;
  - improper neck length;
  - an inappropriate forward angle, referred to as anteversion, of the neck; and
  - improper placement of the hip cup, which can include an incorrect forward angle.
- Leg length discrepancy. Leg length discrepancy occurs when one leg of the patient is longer than the other post-surgery. This can result from a neck angle or femoral component length that is substantially different from the patient's native anatomy or from incorrect placement of the femoral component. Leg length discrepancy can lead to pain and muscle fatigue and is a frequent cause of patient complaints.

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

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

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

- a femoral component made of a single metal piece, or monoblock, that incorporates both stem and neck, which includes a customized neck angle and length designed to match the patient's native anatomy, along with a standard head;
- a hip cup along with a polyethylene acetabular liner; and
- a set of single-use, patient-specific acetabular and femoral iJigs for placement of the acetabular and femoral components with the proper anteversion to both the femur and the hip cup.

We believe that our customized iTotal Hip monoblock femoral component has the same strength as the femoral component of a standard monoblock, or non-modular, off-the-shelf hip implant while at the same time addressing the variability of patients' femoral neck shapes. We believe that the customized nature of our implant will appeal to many surgeons who used modular hips in the past. In addition, we believe the combination of our

customized implant paired with patient-specific iJigs and patient-specific placement of the acetabular cup and the femoral component will help address the problems of hip dislocation and leg length discrepancy associated with off-the-shelf implants.

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

Our proprietary iJigs

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

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

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

Clinical studies

In evaluating the clinical and economic benefits of our customized knee implants, we consider results obtained from studies sponsored by us, conducted by orthopedic surgeons who are paid consultants to us and conducted independently by orthopedic surgeons, including studies that compare our customized knee implants with off-the-shelf knee implants. As of February 29, 2016, there were 8 peer-reviewed journal articles and 26 abstracts either presented or accepted for presentation at conferences reporting on the results of clinical studies of our customized knee implants. Of the published or presented studies known to us that compared our knee replacement product to an off-the-shelf product, most reported either that the performance of our knee replacement product was superior to an off-the-shelf product on the reported measures or that there were no statistically significant differences detected between the performance of our knee replacement product and an off-the-shelf knee replacement product on those measures.

The following provides our summary of the findings of several of these studies that relate to our iTotal CR product and that we considered in forming our views as to the clinical and economic benefits of our customized knee implants.

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

- patients in the iTotal CR group showed statistically significantly lower blood transfusion rates (p=0.005) and adverse event rates at discharge (p=0.003) as compared to patients in the off-the-shelf implant group;
- risk-adjusted odds ratios indicated that patients in the off-the-shelf implant group were 4.6 times more likely to experience a blood transfusion and 4.4 times more likely to have an adverse event at discharge than patients in the iTotal CR group;
- a statistically significantly greater percentage (p=0.037) of patients in the iTotal CR group (42%) were discharged in fewer than three days following surgery than patients in the off-the-shelf group (30%);
- when discharge disposition was analyzed, a statistically significantly lower percentage (p<0.01) of patients in the iTotal CR group were discharged to acute care facilities as compared to patients in the off-the-shelf implant group; and
- there was a greater than $800 total cost of care savings per patient in the iTotal CR group compared to patients in the off-the-shelf implant group after including the estimated average cost of the pre-operative CT scan for patients in the iTotal CR group, primarily due to the assumed savings resulting from the more favorable discharge disposition of patients in the iTotal CR group compared to patients in the off-the-shelf implant group.

We provided financial support for this study. At the time this study was conducted, one of the authors of this study was a paid consultant to us.

Improved clinical outcomes and greater patient satisfaction. We reviewed a presentation from the 2015 ICJR World Arthroplasty Congress that described an investigator-initiated, matched-pair, retrospective study of 35 patients who had undergone total knee replacement with an iTotal CR and 35 patients who had undergone total knee replacement with an off-the-shelf knee implant. Two surgeons performed these TKAs. For each matched pair, the same surgeon performed the iTotal CR and off-the-shelf procedure. Our summary of the principal findings of the study is as follows:

- patients in the iTotal CR group had statistically significantly faster recovery times (p<0.001) than patients in the off-the-shelf implant group as measured by the average time to complete specified functional activities, such as walking and climbing stairs;
- patients in the iTotal CR group suffered statistically significantly less blood loss than patients in the off-the-shelf implant group, as measured by the differences in average drop in blood hemoglobin at one day (p<0.001), five days (p=0.002) and ten days (p=0.03) post-procedure;
- the average self-reported satisfaction score of patients in the iTotal CR group was 94.3%, compared to 74.2% for the group of patients in the off-the-shelf group, and this difference was statistically significant (p=0.04); and
- the average KOOS, or Knee injury and Osteoarthritis Outcome Score, of patients in the iTotal CR group was 83.0%, compared to 73.7% for the group of patients in the off-the-shelf group, and this difference was statistically significant (p=0.037). KOOS is a validated, self-administered testing instrument used to assess patient outcomes.

This study was conducted by independent orthopedic surgeons.

We also reviewed a presentation from the 2015 International Congress for Joint Reconstruction, or 2015 ICJR Pan-Pacific Congress. For this study, researchers at seven U.S. centers performed an interim analysis using a variety of tests of 295 patients, 166 of whom received an iTotal CR knee replacement and 129 of whom received an off-the-shelf implant. Using a validated functional test known as the Aggregated Locomotor Function test, or ALF Test, patients with ConforMIS iTotal CR knee replacements showed a statistically significantly better ALF score than a comparable group of patients who had undergone surgery with off-the-shelf implants (p=0.04). The ALF Test consists of blinded operators assessing patients' ability to perform various activities of daily living, including walking, standing from a chair and climbing stairs. Additionally, patients in this study completed the 2011 New Knee Society Scoring System, or KSS, questionnaire. KSS is a commonly used surgeon-assessed weighted score, the objective component of which measures factors such as range of motion, alignment, and stability, which are important for regaining functional abilities. Utilizing an odds ratio analytic, the objective KSS score showed that patients with

iTotal CR knee replacements were 1.7 times more likely to obtain an excellent or good objective KSS score compared to off-the-shelf patients and that off-the-shelf patients were 2.6 times more likely to achieve a poor objective KSS score than iTotal patients.

Favorable adverse event rate and outcomes. We reviewed an abstract presented at the 2015 ICJR Pan-Pacific Congress that described a multi-center, prospective study of adverse event rates and outcome scores of 252 patients who had undergone total knee replacement with an iTotal CR. Our summary of the principal findings of the study is as follows:

- the adverse event rate, which included manipulations under anesthesia, or MUA, a procedure used post-operatively to adjust a knee replacement implant to improve its function, transfusions and revisions rates, compared favorably to the adverse event rates reported in separate multi-center studies published on off-the-shelf implants;
- the cumulative rate of MUA was 3.57%, which compared favorably to the 4.6% rate of MUA reported in a separate study of off-the-shelf implants;
- range of motion was slightly reduced from baseline at six weeks post-operatively, but significantly improved from baseline at six months ($p<0.001$) and one year ($p=0.001$) post-operatively;
- patients demonstrated statistically significant improvements from baseline scores ($p<0.05$) on the KOOS and on the objective, function and satisfaction portions of KSS ($p<0.05$), by the six-week time-point, with continued improvement reported at the one-year follow up visit.

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

More accurate alignment. We reviewed a paper published in 2014 in the Journal of Arthroplasty that described an investigator-initiated, retrospective study of 200 patients who had undergone total knee replacements, 100 of whom received an iTotal CR implant and 100 of whom received an off-the-shelf implant. The same surgeon performed all 200 implant procedures, and all of the iTotal CR and off-the-shelf implants had been performed consecutively. Our summary of the principal findings of the study is as follows:

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

This study was conducted by five independent authors and one surgeon who was a paid consultant to us at the time this study was conducted.

A more stable knee implant without abnormal lift off. We reviewed the presentation of an abstract from the 2015 ICJR Pan-Pacific Congress that described a study of 38 patients who had undergone total knee replacement, 24 of whom received an iTotal CR implant and fourteen of whom received an off-the-shelf knee implant. The same surgeon performed all 38 implant procedures. All patients had been assessed following the procedure using the Knee Society Knee Score. Our summary of the principal findings of the study follows. All of the patients had objective Knee Society Knee Score scores greater than 90 out of a maximum score of 100, which is an indication of a clinically successful knee replacement. Patients who had received an iTotal CR showed a post-operative kinematic pattern more typical to that of a normal knee when asked to perform a deep knee bend and chair-rise. Patients with off-the-shelf implants experienced greater variability in their kinematic patterns, differing from the typical kinematic patterns of the normal knee. Thirty-five percent of patients with an off-the-shelf implant experienced abnormal lift off in early to mid-flexion (less than 60), during deep knee bending, while patients with an iTotal CR showed no lift off ($p<0.008$) in this flexion range. We provided financial support for this study. At the time the study was conducted, one of the authors of this study was a paid consultant to us.

Improved function with a more normal kinematic pattern. We reviewed the presentation of an abstract from the 2015 ICJR Pan-Pacific Congress that described a study of 63 patients who had undergone a total knee replacement, 15 of whom received an iTotal CR implant and 24 of whom received an off-the-shelf knee implant from one manufacturer, and 25 of whom received an off-the-shelf knee implant from a second manufacturer. The same surgeon performed all 63 implant procedures. Our summary of the principal findings of the study follows. Patients who received an iTotal CR achieved more normal-like kinematic patterns. During both a deep knee bend and a chair-rise, patients with an iTotal CR achieved more normal motion of their lateral condyle. Twenty-four percent of the patients implanted with the off-the-shelf knee from one manufacturer and 48% of patients implanted with the off-the-shelf knee from the other manufacturer experienced an anterior slide of their lateral condyle during deep knee bend, which is the opposite of normal knee kinematics, while only 7% of iTotal patients exhibited such anterior slide. All iTotal patients were able to achieve a minimum of 90 degrees of weight-bearing flexion, as compared to 75% and 76% respectively for the two off-the-shelf implant brands. Due to the sample size, the results from this study were not statistically significant. We provided financial support for this study. At the time this study was conducted, one of the authors of this study was a paid consultant to us.

Sales and marketing

We market and sell our products in the United States, Germany, the United Kingdom, Austria, Ireland, Switzerland,Singapore and Hong Kong. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Consolidated results of operations—Revenue" in this Annual Report on Form 10-K for a summary of product revenue by geography. We market our products to orthopedic surgeons, hospitals and other medical facilities, including ambulatory surgery centers, and patients. We use direct sales representatives, independent sales representatives and distributors to market and sell our products in the United States, Germany, the United Kingdom and other markets. We expect to expand the size of our sales and marketing capabilities by entering into additional distribution or direct sales arrangements in key territories.

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

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

In the United States, we use a database of surgeons, hospitals and procedure volumes to determine which geographical regions are most commercially attractive. Globally, we look for markets with a high volume of total knee replacements, favorable reimbursement characteristics and an historical openness to advanced technologies.

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

As part of our targeted regional commercial strategy, we identify metropolitan statistical areas, or MSAs, in the United States, in which--based on knee replacement procedure volume, surgeon density, prevailing average selling price for a knee replacement, and other factors--we believe we can become a top-three orthopedic implant supplier, as measured by knee replacement procedure volume. We work to significantly increase our sales in these markets by focusing on high-volume, influential surgeons who use our products. We create a tailored direct marketing strategy to increase consumer awareness in these markets. We believe we have achieved a greater than 10% share by volume of

procedures in a number of these markets. At the end of 2014, we had achieved at least 10% market share of all primary knee replacements performed in 14 MSAs in the United States. We had increased the number of MSAs in which we have at least 10% market share of all primary knee replacements to 22 by the end of 2015.

Further, we intend to market our products to hospitals participating in the Comprehensive Care for Joint Replacement Model, or CJR, implemented by the Centers for Medicare and Medicaid Services. The CJR program is intended to push hospitals to manage post-acute care costs by establishing a target episode of care prices for each hospital participant which includes payment for all related services received by Medicare beneficiaries through 90 days post-operatively. Hospitals would continue to be paid as they are now, however, on a yearly basis Medicare will reconcile actual prices against the target prices under CJR and participating hospitals will either keep savings or owe Medicare for price overages. Since publication of the proposed rule in July 2015, we have signed new contracts that allow us access to more than 50 additional hospitals that will participate in the CJR program. We plan to add more hospitals that are involved with the CJR program and we are adding participation in the Medicare CJR as a criterion for our targeted regional marketing strategy.

Research and development

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

- new product development;
- enhancements of existing products and software;
- improvements in our iFit technology platform to further advance production efficiency and decrease the production time from receipt of an order to delivery of our product; and
- advancements of our iFit technology platform that will enable us to provide our customized products to a larger customer base, which we refer to as mass customization.

Our team of 39 full-time research and development employees has extensive experience in biomechanical engineering, manufacturing engineering and software engineering and development. A significant portion of our research and development activities involves the development of proprietary algorithms and computer software that underpins our entire iFit technology platform. For the years ended December 31, 2015, 2014 and 2013, company-sponsored research and development expenses were $17 million, $15 million and $14 million, respectively. When we develop a new product or seek to improve our existing products, our team of biomechanical and software engineers typically collaborates closely with experienced orthopedic surgeons and other independent scientists. After we complete the development of a new product or an improvement to an existing product, we seek regulatory clearance before introducing the product into patients.

Manufacturing

We conduct our manufacturing activities in state-of-the-art design and manufacturing facilities in Bedford and Wilmington, Massachusetts. We completed the transfer of operations that were previously conducted in a facility in Burlington, Massachusetts, to our Wilmington facility in August 2015.

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

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

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

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

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

iFit 3D printing

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

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

We have received FDA clearance to apply our iFit 3D printing technology to manufacture the metal femoral implant component for our iTotal CR using direct metal laser sintering, or DMLS, using raw material that meets or exceeds the ASTM F-75 specification for chemical content and mechanical properties. ASTM F-75 is the accepted material standard for knee replacement femoral components. We are currently in the process of integrating DMLS into our manufacturing process, and plan to employ the technology selectively in a manner that complements our existing processes and reduces manufacturing costs.

Quality assurance

We apply a variety of automated and manual quality controls to our iJigs, implant components and other instruments we supply to ensure that our products conform to their specifications. Members of our quality department also inspect our devices at various steps during the manufacturing cycle to facilitate compliance with specifications. Our quality department periodically audits our suppliers to ensure conformity with our specifications and with our policies and procedures for our devices. On August 31, 2015, we announced a voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems. The recalled products were manufactured and distributed from our Wilmington manufacturing facility between July 18, 2015 and August 28, 2015. We isolated the root cause to a step in our ethylene oxide sterilization process conducted by a vendor. We have since completed final testing and implemented corrective actions, and we resumed normal production in October 2015.

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

Intellectual property

Protection of our intellectual property is an important priority for our company. Our success depends in part on our ability to obtain and maintain proprietary rights for our products and technology, to operate without infringing the

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proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our intellectual property position by, among other things, filing U.S. and certain foreign patent applications related to our products and technology where patent protection is available. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

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

Patent rights

As of February 29, 2016 we owned or exclusively in-licensed 195 issued patents around the world, including 131 patents issued in the United States and 64 foreign patents.

- With respect to the patents that we own relating primarily to our customized joint replacement implants, the first nonprovisional application was filed in 2002 claiming priority to a provisional application filed in 2001 and is expected to expire in 2022 and the other patents are expected to expire between 2022 and 2030.
- With respect to the patents that we own relating primarily to our patient-specific instrumentation, the first nonprovisional application was filed in 2002 claiming priority to a provisional application filed in 2001 and is expected to expire in 2022 and the other patents are expected to expire between 2022 and 2031.
- With respect to the patents that we own relating primarily to our iFit technology platform, the first nonprovisional application was filed in 2002 claiming priority to a provisional application filed in 2001 and is expected to expire in 2022 and the other patents are expected to expire between 2022 and 2032.
- With respect to the patents that we exclusively in-license, the first nonprovisional application was filed in 2000 claiming priority to a provisional application filed in 1998 and is expected to expire in 2019 and the other patents are expected to expire between 2019 and 2021.

As of February 29, 2016, we owned or exclusively in-licensed 313 patent applications, including 109 patent applications pending in the United States and 204 foreign patent applications.

- With respect to the patent applications that we own relating primarily to our customized joint replacement implants, patient-specific instrumentation, and our iFit technology, the first were filed in 2001 and if patents issue on these applications, they would be expected to expire in 2022 and if patents issued on the other patent applications, such patents would be expected to expire between 2023 and 2035.
- With respect to the patent applications that we exclusively in-license, the first was filed in 1998 and if a patent issues on this application, it would be expected to expire in 2019. If patents issue on the other patent applications, such patents would be expected to expire between 2019 and 2026.

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

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

Licenses from others

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

Patent litigation

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

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

On October 21, 2015, a complaint for patent infringement was filed against us in the United States District Court for the District of Delaware by Orthopedic Innovations, Inc., which the complaint states is a subsidiary of Wi-LAN Technologies Inc. The complaint alleges that our iUni G2 and iDuo G2 partial knee replacement surgical techniques infringe one or more claims of United States Patent No. 6,575,980. The plaintiff seeks damages, including for willful infringement, attorney’s fees, costs and a permanent injunction. We believe that none of our products or services infringes the plaintiff’s patent. The plaintiff served the complaint on February 17, 2016. We intend to deny liability and to defend ourselves vigorously. There can be no assurance, however, that we will be successful. An adverse resolution of the lawsuit could have a material adverse effect on our business, financial condition or results of operations. We are presently unable to predict the outcome of the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit.

On February 29, 2016, we filed a lawsuit against Smith & Nephew, Inc. (“Smith & Nephew”) in the United States District Court for the District of Massachusetts Eastern Division. The lawsuit alleges that Smith & Nephew’s Visionaire® patient-specific instrumentation, as well as the implants systems used in conjunction with the Visionaire instrumentation, infringe eight of our patents, and requests monetary damages for willful infringement and a permanent injunction. We are presently unable to predict the outcome of the lawsuit and there can be no assurance that we will be successful in this litigation. We may also be subject to counterclaims including, but not limited to allegations that the asserted patents are not infringed, are invalid, and or are unenforceable.

Licenses to others

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

License agreement with MicroPort

In April 2015, we entered into a worldwide license agreement with MicroPort. Under the terms of this license agreement, we granted a perpetual, irrevocable, non-exclusive license to MicroPort to use patient specific instrument technology covered by our patents and patent applications with off-the-shelf implants in the knee. This license does not extend to patient-specific implants. This license agreement provides for the payment to us of a fixed royalty at a high single to low double digit percentage of net sales on patient specific instruments and associated implant components in the knee, including MicroPort's Prophecy patient specific instruments used with its Advance and Evolution implant components. This license agreement also provided for a single lump-sum payment by MicroPort to us of low-single digit millions of dollars upon entering into the license agreement, which has been paid. This license agreement will expire upon the expiration of the last to expire of our patents and patent applications licensed to

MicroPort, which currently is expected to occur in 2029.

License agreement with Wright Medical

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

Trademarks

As of February 29, 2016, we have filed 130 trademark registrations in the United States and in other major markets worldwide, including the following marks: ConforMIS, iFit, iTotal, iDuo, and iUni. We have 43 trademark applications pending in the United States and in other major markets worldwide.

Competition

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

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

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

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

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

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

Regulatory requirements

Our products are medical devices that are subject to extensive regulation by government authorities in the United States and in other countries and jurisdictions, including the EU. These governmental authorities regulate the marketing and distribution of medical devices in their respective geographies. The regulations cover the entire life cycle of the product, including the research, development, testing, manufacture, quality control, packaging, storage, labeling, advertising and promotion of the devices. In addition, post-approval monitoring and reporting, as

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well as import and export of medical devices, are subject to regulatory requirements. The processes for obtaining regulatory approvals or clearances in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

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

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

Unless an exemption applies, a new medical device may not be marketed in the United States unless it has been cleared by the FDA through filing of a 510(k) premarket notification, or 510(k), or approved by the FDA pursuant to a premarket approval application, or PMA. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes depending on the level of control necessary to assure the safety and effectiveness of the device. Class I devices have the lowest level or risk associated with them, and are subject to general controls, including labeling, premarket notification and adherence to the QSR. Class II devices are subject to general controls and special controls, including performance standards. Class III devices, which have the highest level of risk associated with them, are subject to most of the aforementioned requirements as well as to premarket approval. Most Class I devices and some Class II devices are exempt from the 510(k) requirement, although manufacturers of these devices are still subject to registration, listing, labeling and QSR requirements.

To date, we have used exclusively the 510(k) premarket notification process to obtain regulatory clearance from the FDA for the marketing and sale of our joint replacement products in the United States. All of our currently marketed products are Class II devices marketed pursuant to 510(k) clearances. We expect that our iTotal Hip product will be classified as a Class II device. We submitted an application for 510(k) clearance of iTotal Hip in 2015. We cannot predict if or when we will receive clearance or initiate the commercial launch of iTotal Hip. We expect that iTotal Hip will be our next new product introduction after iTotal PS.

510(k) premarket notification

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

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

Modifications to a 510(k)-cleared medical device may require the submission of another 510(k) or a PMA if the changes could significantly affect safety or effectiveness or constitute a major change in the intended use of the device. Modifications to a 510(k)-cleared device frequently require the submission of a traditional 510(k), but modifications meeting certain conditions may be candidates for FDA review under a Special 510(k). If a device modification requires the submission of a 510(k), but the modification does not affect the intended use of the device or

alter the fundamental technology of the device, then summary information that results from the design control

process associated with the cleared device can serve as the basis for clearing the application. A Special 510(k) allows a manufacturer to declare conformance to design controls without providing new data. When the modification involves a change in material, the nature of the "new" material will determine whether a traditional or Special 510(k) is necessary.

Premarket approval application

The PMA process for approval to market a medical device is more complex, costly and time consuming than the 510(k) clearance procedure. A PMA must be supported by extensive data, including technical, preclinical, clinical, manufacturing, control and labeling information, that demonstrate the safety and effectiveness of the device for its intended use. After a PMA is submitted, the FDA has 45 days to determine whether it is sufficiently complete to permit a substantive review. If the PMA is complete, the FDA will file the PMA. The FDA is subject to performance goal review times for PMAs and may issue a decision letter as a first action on a PMA within 180 days of filing, but if it has questions, it will likely issue a first major deficiency letter within 150 days of filing. It may also refer the PMA to an FDA advisory panel for additional review, and will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the QSR, either of which could extend the 180-day response target. In addition, the FDA may request additional information or request the performance of additional clinical trials before it will reconsider the approval of the PMA or as a condition of approval, in which case the trials must be completed after the PMA is approved.

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

Investigational device exemption

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

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

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

Post-marketing restrictions and enforcement

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

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

Review and approval of medical devices in the EU

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

To date, we have used the CE Marking process to satisfy the conformity standards required to market and sell our joint replacement products in the EU. The Notified Body that has conducted conformity assessments with respect to our joint replacement products is the BSI.

Medical device manufacturers must carry out a clinical evaluation of their medical devices to demonstrate conformity with the relevant Essential Requirements. This clinical evaluation is part of the product's technical file. A clinical evaluation includes an assessment of whether a medical device's performance is in accordance with its intended use, that the known and foreseeable risks linked to the use of the device under normal conditions are minimized and acceptable when weighed against the benefits of its intended purpose. The clinical evaluation conducted by the manufacturer must also address any clinical claims, the adequacy of the device labeling and information (particularly claims, contraindications, precautions and warnings) and the suitability of related instructions for use. This assessment must be based on clinical data, which can be obtained from clinical studies conducted on the devices being assessed, scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or both clinical studies and scientific literature.

With respect to implantable devices or devices classified as Class III in the EU, the manufacturer must conduct clinical studies to obtain the required clinical data, unless reliance on existing clinical data from similar devices can be justified. As part of the conformity assessment process, depending on the type of devices, the Notified Body will review the manufacturer's clinical evaluation process, assess the clinical evaluation data of a representative sample of the devices' subcategory or generic group, or assess all the clinical evaluation data, verify the manufacturer's assessment of that data and assess the validity of the clinical evaluation report and the conclusions drawn by the manufacturer. The conduct of clinical studies to obtain clinical data that might be required as part of the described clinical evaluation process can be expensive and time-consuming. To date, we have not been required to conduct any

of these clinical studies to obtain clinical data as part of the clinical evaluation process.

Even after we receive a CE Certificate of Conformity enabling us to affix the CE Mark on a product and to sell our product in the EEA countries, a Notified Body or a competent authority may require post-marketing studies of

our product. Failure to comply with such requirements in a timely manner could result in the withdrawal of our CE Certificate of Conformity and the recall or withdrawal of our product from the market in the EU, which would prevent us from generating revenue from sales of that product in the EEA. Moreover, each CE Certificate of Conformity is valid for a maximum of five years, but more commonly three years. Our current CE Certificates of Conformity are valid through August 5, 2016 for our iTotal CR product, February 12, 2017 for our iUni product, June 11, 2019 for our iDuo product and March 5, 2020 for our iTotal PS product. At the end of each period of validity we are required to apply to the Notified Body for a renewal of the CE Certificate of Conformity. There may be delays in the renewal of the CE Certificate of Conformity or the Notified Body may require modifications to our products or to the related Technical Files before it agrees to issue the new CE Certificate of Conformity.

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

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

Marketing and sales considerations in the EU

In the EU, medical devices may be promoted only for the intended purpose for which the devices have been CE Marked. Failure to comply with this requirement could lead to the imposition of penalties by the competent authorities of the EU Member States. The penalties could include warnings, orders to discontinue the promotion of the medical device, seizure of the promotional materials and fines. Promotional materials must also comply with various laws and codes of conduct developed by medical device industry bodies in the EU governing promotional claims, comparative advertising, advertising of medical devices reimbursed by the national health insurance systems and advertising to the general public.

Product vigilance and post-approval monitoring in the EU

Additionally, all manufacturers placing medical devices into the market in the EU are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the competent authority in whose jurisdiction the incident occurred. In the EU, manufacturers must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant authorities of the EU countries, and manufacturers are required to take field safety corrective actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. See "Risk Factors—Risks related to regulatory approval—If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions."

Third-party reimbursement

In the United States and most other major joint implant markets, third-party payors, including government health programs, commercial health insurers and managed care organizations, reimburse hospitals and other medical

facilities an aggregate amount for all elements of a joint replacement procedure, including operating room time, patient care and the joint replacement product. As a result, our products generally are not reimbursed

separately, but instead are subject to the limits imposed by third-party payors on the coverage and reimbursement of procedures that utilize our products.

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

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

Healthcare laws and regulations

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

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Health Care Reform Law will require manufacturers of devices, drugs and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Financial information about segments and geographic areas

We operate as one reportable segment as described in Note B to the Consolidated Financial Statements included in this Annual Report on Form 10-K. The countries in which we have local revenue generating operations have been combined into the following geographic areas: the United States (including Puerto Rico), Germany, and the rest of the world, which consists of Europe predominately (including the United Kingdom) and other foreign countries. Sales are attributable to a geographic area based upon the customer's country of domicile. Net property, plant and equipment are based upon physical location of the assets. Additional financial information about geographic areas is included in Note O to the Consolidated Financial Statements included in this Annual Report on Form 10-K.

We are exposed to risks associated with international operations, including exchange rate fluctuations, regional and country-specific political and economic conditions, foreign receivables collection concerns, trade protection measures, import or export requirements, tax risks, staffing and labor law concerns, intellectual property protection risks, differing regulatory requirements, government-managed healthcare systems, government-mandated pricing and reimbursement schemes, government-mandated collection periods, patient privacy laws and regulations, and other data privacy laws and regulations.

Employees

As of February 29, 2016, we had 387 employees, including 380 full-time employees, 102 of whom were engaged in sales and marketing, 30 in research and development, 173 in manufacturing and service, 43 in regulatory, clinical affairs and quality activities and 32 in general administrative and accounting activities. None of our employees are covered by a collective bargaining agreement. We consider our relationships with our employees to be good.

Our corporate information

We were incorporated under the laws of the State of Delaware in 2004. Our principal executive offices are located at 28 Crosby Drive, Bedford, MA 01730, and our telephone number is (781) 345-9001. Our website is http://www.conformis.com.

Available information

We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. You can find, copy and inspect information we file at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. You can review our electronically filed reports and other information that we file with the SEC on the SEC's web site at http://www.sec.gov. We also make available, free of charge on our website www.conformis.com, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. The information contained on, or that can be accessed through, our website is not a part of or incorporated by reference in this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

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

Risks related to our financial position

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

We have incurred significant net operating losses in every year since our inception and expect to incur net operating losses for the next several years. Our net loss was $57 million for the year ended December 31, 2015, $46 million for the year ended December 31, 2014 and $48 million for the year ended December 31, 2013. As of December 31, 2015, we had an accumulated deficit of $325 million. We expect to continue to incur significant product development, clinical and regulatory, sales and marketing, manufacturing and other expenses as our business continues to grow and we expand our product offerings. Additionally, our general and administrative expense will continue to increase due to the additional operational and reporting costs associated with our expanded operations and being a public company. We will need to generate significant additional revenue to achieve and maintain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. In addition, our growth may slow, for reasons described in these risk factors. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations.

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

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

- expansion of our sales and marketing efforts;
- expansion of our manufacturing capacity;
- funding research, development and clinical activities related to our existing products and product platform, including iFit design software and product support;
- funding research, development and clinical activities related to new products that we may develop, including other joint replacement products;
- pursuing and maintaining appropriate regulatory clearances and approvals for our existing products and any new products that we may develop; and
- preparing, filing and prosecuting patent applications, and maintaining and enforcing our intellectual property rights and position.

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

We anticipate that our principal sources of funds will be revenue generated from the sales of our products and revenues that we may generate in connection with licensing our intellectual property. In November 2014, we borrowed the first of two $10 million term loans , referred to as the SVB/Oxford Term Loan A, under a loan and security agreement with Silicon Valley Bank, or SVB, and Oxford Finance, LLC, or the 2014 Secured Loan Agreement. In September 2015, we voluntarily prepaid the SVB/Oxford Term Loan A in full and terminated our right to draw down the term loans and any security interest in favor of Oxford Finance, LLC. In December 2015, we also terminated a revolving line of credit we had from SVB. For further information regarding this facility, see "Note K—Debts and Notes Payable—2014 Secured Loan Agreement."

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.

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We may need to engage in equity or debt financings to secure additional funds. We may not be able to obtain additional financing on terms favorable to us, or at all. To the extent that we raise additional capital through the future sale of equity or convertible debt, the ownership interest of our stockholders will be diluted. The terms of these future equity or debt securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders or involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures.

Risks related to our business, industry and competitive position

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

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

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

We may allocate significant amounts of capital toward products or technologies for which market demand is lower than anticipated and, as a result, abandon such efforts. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, or if we expend capital on projects that are not successful, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, and we may even have to scale back our operations. We can also be negatively affected by general economic conditions. Because of our limited operating history, we may not have insight into trends that could emerge and negatively affect our business. As a result of these or other risks, our business strategy might not be successful.

We have derived nearly all of our revenues from sales of a limited portfolio of knee replacement products and may not be able to maintain or increase revenues from these products.

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

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

We are expanding our offerings to include an additional joint replacement product for the knee, the iTotal PS, which we launched commercially, and are developing our first hip replacement product, the iTotal Hip, for which we filed 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. Any factors that delay the commercial launch of, including the process for obtaining regulatory clearance for, our additional products, or result in sales of our additional products increasing at a lower rate than expected, could adversely affect our business, financial condition and operation results. In addition, even if we do launch these products, there can be no assurance that these products will be accepted in the market or commercially successful or profitable.

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

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

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

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

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

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- more expansive portfolios of intellectual property rights and greater funds available to engage in legal action.

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

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

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

In order to increase our gross margins we will need, among other things, to:

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

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

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

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

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

- comfort and experience with competitive products;
- perceived differences in surgical technique;
- existing relationships with competitors, competitive sales representatives and competitive distributors;

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

If clinical, functional or economic data does not demonstrate the benefits of using our products, surgeons may not use our products. In such circumstances, we may not achieve expected sales and may be unable to achieve profitability. To understand the clinical, functional and economic benefits of using our products, surgeons may refer to published studies sponsored by us, conducted by orthopedic surgeons who are paid consultants to us or conducted independently by orthopedic surgeons comparing our customized products to off-the-shelf products. To the extent such studies do not report favorably on our products, surgeons may be less likely to use our products. We are aware of one clinical study conducted by a single surgeon and involving only 21 iTotal CR patients, in which our iTotal CR product performed less well than off-the-shelf knee replacement products. This study compared our iTotal CR product to posterior-stabilized and non-cemented rotating platform implants, which we believe makes the comparison of questionable value. The measures on which our iTotal CR product performed less well than the off-the-shelf products were range of motion at six weeks (although our iTotal CR product performed equally well at minimum one year follow-up) and manipulation under anesthesia, or MUA, a procedure used post-operatively to adjust a knee replacement implant to improve its function. In a subsequent multi-center study of our iTotal CR product involving 252 patients for which we provided financial support, the 3.57% rate of MUA for our iTotal CR product was substantially lower than the 28.6% rate of MUA shown in this earlier and much smaller single-surgeon study. See "Business—Clinical studies" for additional information on this multi-center study. By comparison, the rate of MUA reported in a separate study of off-the-shelf implants was 4.6%.

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

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

and as a result, our sales, revenue and profitability may be adversely affected.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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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. Further, if hospitals participating in the new Medicare CJR program do not use our products in the volumes we anticipate, it may have an adverse impact on our sales going forward.

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

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

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

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

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

In order for surgeons to use our products, the hospitals and other medical facilities where these surgeons treat patients typically require us to enter into purchasing contracts. The process of negotiating a purchasing contract can be lengthy

and time-consuming, require extensive management time and may not be successful. In addition, many of our customers and potential customers are members of group purchasing organizations that are focused on containing costs. Group purchasing organizations negotiate pricing arrangements with medical supply and device manufacturers, and these negotiated prices are made available to a group purchasing organization's affiliated hospitals and other medical facilities. If we do not have pricing agreements with group purchasing organizations,

their affiliated hospitals and other medical facilities may be less likely to purchase our products. Our failure to complete purchasing contracts with hospitals or other medical facilities or contracts with group purchasing organizations may cause us to lose market share to our competitors and could have a material adverse effect on our sales, financial condition, results of operations and cash flows. Our competitors may also elect to lower their prices in select accounts, thereby rendering our products non-competitive on the basis of price, with resulting losses in sales to these accounts.

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

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

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

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

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

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

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

We depend on relationships with independent sales representatives and distributors of orthopedic implants and instrumentation for the marketing and sales of our products in geographic regions that are not targeted by our direct sales force, including parts of the United States, Switzerland, Hong Kong and Singapore. Revenues generated from the sales of our products by independent sales representatives represented approximately 61% of our total revenue from sales of our products in the United States for the year ended December 31, 2015, 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, 2015, 2014 and 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 years ended December 31, 2015 and 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, 2015, 2014 and 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. economy continues to recover from the worst recession in decades, unemployment and consumer confidence have not rebounded as quickly as in some prior recessions, resulting in reduced numbers of insured patients and the deferral of some elective joint replacement procedures. Global economic conditions remain uncertain. Much of Europe remains in recession as the credit ratings of several European countries and the possibility that certain European Union member states will default on their debt obligations have contributed to significant uncertainty about the stability of global credit and financial markets. In addition, the Chinese economy has recently showed slowing growth, and economies of oil producing regions are weakening, in some cases rapidly and significantly as a result of volatility in the supply and price of oil. Challenges and pressures in the global economy may ultimately impact joint replacement procedure volumes, average selling prices and reimbursement rates from third-party payors, any of which could adversely affect our results of operations. Unfavorable economic conditions can depress sales in a given market and may result in actions that adversely affect our margins, constrain our operating flexibility or result in charges which are unusual or non-recurring. Certain macroeconomic events, such as the continuing adverse conditions in the global economy, the recent recessions in Europe, the Eurozone crisis and the softening Chinese economy could have a more wide-ranging and prolonged impact on the general business environment, which could also adversely affect us. These economic developments could affect us in numerous ways, many of which we cannot predict. Among the potential effects could be:

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

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

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

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

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

As of December 31, 2015, we had $481,000 of outstanding term loans under our credit facility with the Massachusetts Development Finance Agency, referred to as the MDFA facility.

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

The MDFA facility is secured by a lien over certain of our equipment. The security interests granted over our assets could limit our ability to obtain additional debt financing. In addition, the documentation governing the MDFA facility contain negative covenants restricting certain of our activities, including limitations on dispositions of the secured assets, mergers or acquisitions, incurring indebtedness or liens, paying dividends and certain other business transactions. Future debt securities or other financing arrangements could contain similar or more restrictive negative covenants. See "Note K—Debt and Notes Payable—$1.4 million term loan—Massachusetts Development Finance Agency" to the Consolidated Financial Statements included in this Annual Report on Form 10-K for additional information on this facility.

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

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

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

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

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to engage these individuals as our advisors and in connection with future development and training efforts. If we are unable to establish and maintain our relationships with consultants, surgeons and medical personnel, our ability to develop and sell new and improved products could decrease, and our future operating results could be unfavorably affected.

Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, business interruption insurance, property insurance and workers' compensation insurance. The cost of maintaining product liability insurance on implantable medical devices has increased substantially over the past few years and could continue to substantially increase, due to general market trends, as part of an evaluation of our specific loss history and other factors. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. Similarly, if we exhaust our current insurance coverage for any given policy period, we would be required to operate our business without indemnity from commercial insurance providers for any claims made that are attributable to that policy period.

Consolidation in the healthcare industry could lead to demands for price concessions or the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or operating results.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and likely will continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for some of our customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products and may adversely impact our business, financial condition or operating results.

Risks related to our manufacturing

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

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

On August 31, 2015, we announced a voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems. The recalled products were manufactured and distributed from our Wilmington manufacturing facility between July 18, 2015 and August 28, 2015. We isolated the root cause to a step in our ethylene oxide sterilization process conducted by a vendor. We have since completed final testing and implemented corrective actions, and we resumed normal production in October 2015. This recall and the resulting temporary reduction in capacity has adversely affected our business and may continue to adversely affect our business, including through the financial impact from lost sales of the recalled products, reduction of our production capacity over the period of our investigation and resolution of the root cause of the recall, commercial disruption, damage to our reputation with orthopedic surgeons,

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consumers, healthcare providers, distributors and other business partners and the filing of a putative class action complaint against us and certain of our officers alleging violations of securities laws.

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

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

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

- acquiring raw materials for 3D printing;
- deploying new manufacturing processes, including DMLS 3D printing;
- acquiring 3D printers, especially DMLS 3D printers;
- managing production yields;
- maintaining quality control and assurance;
- maintaining component availability;
- maintaining adequate control policies and procedures;
- hiring and retaining qualified personnel; and
- complying with state, federal and foreign regulations.

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

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

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

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

We currently depend on sole source suppliers for the supply of polymer and metal powders. These sole source suppliers may be unwilling or unable to supply the powders to us reliably, continuously and at the levels we

anticipate or are required by the market. We may incur added costs or delays in identifying and qualifying replacement suppliers. In addition, because these suppliers supply large portions of the markets for these materials, there is competition for such supply. As a result of such competition, the prices for these supplies may increase and their availability to us may decrease.

If any of our key suppliers were to decide to discontinue or limit the supply of a raw material that we use, the unanticipated change in the availability of supplies could cause delays in, or loss of, sales, increased production or related costs and damage to our reputation. In addition, because we use a limited number of suppliers, price increases by our suppliers may have an adverse effect on our results of operations, as we may be unable to find an alternative supplier who can supply us at a lower price. As a result, the loss of a limited source supplier could adversely affect our relationships with our customers and our results of operations and financial condition.

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

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

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

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

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

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

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

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

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

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

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

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

Risks related to our international operations

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

We sell our products internationally in Germany, the United Kingdom, Austria, Ireland, Switzerland, Singapore and Hong Kong. We expect that our international activities will increase over the foreseeable future as we continue to pursue opportunities in international markets. During each of the years ended December 31, 2015, 2014 and 2013 approximately 25%, 29% and 29% of our revenue was attributable to our international customers, respectively, and as of December 31, 2015, approximately 5% of our employees were located outside the United States. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subjects us to extensive U.S., 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.

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

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

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

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

Risks related to managing our future growth

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

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research and development, manufacturing, manufacturing engineering, regulatory affairs, sales, marketing and distribution and general administration, some of whom we will require to have specific technical skills that are in high demand. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities to devote time to managing these growth activities. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional

qualified personnel. Our inability to effectively manage the expansion of our operations may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional products. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced, and we may not be able to implement our business strategy. In addition, we may consider further expanding our operations through potential acquisitions. Potential and completed acquisitions and strategic investments involve numerous risks, including diversion of management's attention from our core business, problems assimilating the purchased technologies or business operations and unanticipated costs and liabilities. Our future financial performance and our ability to commercialize products and compete effectively will depend, in part, on our ability to effectively manage any future growth, including growth through acquisitions.

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

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

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

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

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

Risks related to our intellectual property and potential litigation

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

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

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

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

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

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

In particular, on February 29, 2016, we filed a lawsuit against Smith & Nephew, Inc. (“Smith & Nephew”) in the United States District Court for the District of Massachusetts Eastern Division. The lawsuit alleges that Smith & Nephew’s Visionaire® patient-specific instrumentation, as well as the implants systems used in conjunction with the Visionaire instrumentation, infringe eight of our patents, and requests monetary damages for willful infringement and a permanent injunction. This lawsuit is described in more detail in Part II, Item 3, Legal Proceedings of this Annual Report on Form 10-K. While we believe we have a meritorious case, we cannot predict the outcome of this lawsuit.

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

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

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

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

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

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

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

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

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

Our commercial success depends in part on not infringing the patents or violating the other proprietary rights of others and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or products, including interference or derivation proceedings before the U.S. Patent and Trademark Office. Significant litigation regarding patent rights occurs in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that may prevent, limit or otherwise interfere with our ability to make, use and sell our products. Our ability to defend ourselves or our third-party suppliers may be limited by our financial and human resources, the availability of reasonable defenses, and the ultimate acceptance of our defenses by the courts or

juries. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, so there may be applications of others now pending of which we are unaware that may later result in issued patents that may prevent, limit or otherwise interfere with our ability to make, use or sell

our products. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved and the uncertainty of litigation increase the risk of business assets and management's attention being diverted to patent litigation.

We have received in the past, and may receive in the future, particularly as a public company, communications from various industry participants and patent holders alleging our infringement of their patents, trade secrets or other intellectual property rights or offering licenses to such intellectual property. We are aware of non-practicing entities that are seeking to exploit patents in the orthopedic area. In particular, in October 2015 we were sued for patent infringement by one such non-practicing entity, Orthopedic Innovations, Inc., alleging that our iUni G2 and iDuo G2 partial knee replacement surgical techniques infringe an existing patent. Among other relief, the plaintiff seeks damages for willful infringement, attorney’s fees, costs and a permanent injunction. This lawsuit is described in more detail in Part II, "Item 3—Business—Legal Proceedings," of this Annual Report on Form 10-K. While we believe we have meritorious defenses, we cannot predict the outcome of this lawsuit.

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

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive or infeasible; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in the joint replacement industry grows, the possibility of intellectual property infringement claims against us increases. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages, which may be increased up to three times of awarded damages, or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition.

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

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

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we will not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to enable us to terminate infringing activities.

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

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

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

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

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

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for knee and hip replacement procedures. Knee replacement surgery involves significant risk of serious complications, including bleeding, infection, instability, dislocation, nerve injury and death. Hip replacement surgery involves significant risk of serious complications including bleeding, infection, dislocation, leg length discrepancy, nerve injury and death. In addition, joint replacement surgery involves product risks, including failures

over time due to polyethylene wear and aseptic loosening, which is a condition caused by wear debris generated by the implant. We or our suppliers could suffer breaches to our sterilization procedures, which could cause contamination of the affected components and products we market and ultimately could cause infections in

patients. Moreover, patients may be dissatisfied with the results of joint replacement surgery even if there is no medical complication. Furthermore, if orthopedic surgeons are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients.

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

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

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

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

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

Risks related to government regulation

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

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

- untitled letters, warning letters, fines, injunctions or civil penalties;
- termination of distribution authorizations;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal of the FDA or other regulators to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products;

- withdrawal of the CE Certificates of Conformity, which authorize us to apply the CE Mark to our products and are necessary to sell our products within the European Economic Area, or EEA, or delay in obtaining these certificates; or
- in the most serious cases, criminal penalties.

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

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

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

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

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

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

- changes in governmental regulations or administrative actions; and
- the interim or final results of the clinical trials may be inconclusive or unfavorable as to safety or effectiveness.

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

In the United States, all of our FDA-cleared products have been cleared without the use of a PMA under the 510(k) clearance process. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. The FDA may demand that we obtain a PMA prior to marketing certain of our future products. In addition, if the FDA disagrees with our determination that a product we currently market is eligible for clearance under the premarket notification process of Section 510(k) of the FDCA, the FDA may require us to submit a PMA in order to continue marketing the product. Further, even with respect to those future products where a PMA is not required, we may not be able to obtain the 510(k) clearances with respect to those products.

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

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

As part of the conformity assessment process, depending on the type of device, an entity authorized to conduct the conformity assessment, which is referred to as a Notified Body, will review the manufacturer's clinical evaluation process, assess the clinical evaluation data of a representative sample of the device's subcategory or generic group, or assess all the clinical evaluation data, verify the manufacturer's assessment of that data and assess the validity of the clinical evaluation report and the conclusions drawn by the manufacturer. The conduct of clinical studies to obtain clinical data that might be required as part of the described clinical evaluation process can be expensive and time-consuming. To date, we have not been required to conduct any of these clinical studies to obtain clinical data as part of the clinical evaluation process.

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

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

studies in a timely manner could result in the revocation of the 510(k) clearance or PMA approval for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

Even after we receive a CE 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 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.

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. In addition, we must report corrections and removals to the FDA where the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act caused by the device that may present a risk to health, and maintain records of other corrections or removals. If we receive regulatory clearance or approval of additional products in the future, the clearance or approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of clearance or approval, and the accompanying label may limit the approved use of our product, which could limit sales of the product.

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

- litigation involving patients who underwent procedures using our products;
- restrictions on such products, manufacturers or manufacturing processes;

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

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

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

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

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

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

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

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

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

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

The British Standards Institute, or BSI, an independent global notified body, conducts annual assessments of our quality management system in order to confirm that our quality management system complies with the requirements of ISO13485 in all material respects and periodic full recertification audits of our quality management system in order to confirm that we comply with the requirements of the Medical Devices Directive 93/42/EEC. Our last full recertification audit was completed in 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, which could harm our business.

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

Additionally, all manufacturers placing medical devices in the market in the EU are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the competent authority in whose jurisdiction the incident occurred. In the EU, we must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant National Competent Authorities of the EU countries, 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.

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

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated.

On August 31, 2015, we announced a voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems. The recalled products were manufactured and distributed from our Wilmington manufacturing facility between July 18, 2015 and August 28, 2015. We isolated the root cause to a step in our ethylene oxide sterilization process conducted by a vendor. We have since completed final testing and implemented corrective actions, and we resumed normal production in October 2015. This recall and the resulting temporary reduction in capacity has adversely affected our business and may continue to adversely affect our business, including by potentially damaging our reputations with consumers, healthcare providers, distributors and other business partners. We have also experienced other limited recalls in the past related to manufacturing defects, labeling updates and packaging inconsistencies.

A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. We are also

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

FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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

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

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

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

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

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

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

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

Recent political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health programs, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the United States and foreign

governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. Such legislation and regulations may result in decreased reimbursement for medical devices or the procedures in which they are used, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products, generate sales and become or remain profitable.

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

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

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

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

Risks related to other legal and compliance matters

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

On September 3, 2015, a purported securities class action lawsuit was filed against us, our chief executive officer and chief financial officer in the United States District Court for the District of Massachusetts, alleging, among other things, that the defendants violated federal securities laws by allegedly making misrepresentations or failing to make proper disclosures regarding our manufacturing process prior to our voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems. Among other relief, the plaintiff seeks certification of the class, unspecified compensatory damages, interest, attorneys’ fees, expert fees and other costs. The class action lawsuit is described in more detail in Item 3, Legal Proceedings, of this Annual Report on Form 10-K.

While we believe we have meritorious defenses, we cannot predict the outcome of this lawsuit. There may be additional suits or proceedings brought in the future related to our voluntary recall of specific serial numbers of

patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems.

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

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

The PPACA imposes, among other things, an excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States as of 2013, although this tax has been suspended for 2016 and 2017. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to $20 billion over the next decade. The Internal Revenue Service issued final regulations implementing the tax in December of 2012 that require, among other things, bi-monthly payments if the tax liability exceeds $2,500 for the quarter and quarterly reporting. We are subject to this excise tax and during the years ending December 31, 2015, December 31, 2014 and December 31, 2013, we incurred $0.8 million, $0.7 million and $0.4 million, respectively, in tax expense associated with the medical device tax in the United States, which is included in general and administrative expense. The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law on December 18, 2015, includes a two year moratorium on the medical device excise tax imposed by Internal Revenue Code section 4191. Thus, the medical device excise tax does not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016 and ending on December 31, 2017. It is unclear at this time if the moratorium will be extended, and we are currently subject to the tax after December 31, 2017. Additionally, Congress could terminate the moratorium or further change the law related to the medical device tax, in a manner that could adversely affect us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks related to our common stock

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

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

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

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

- a slowdown in the medical device industry or the general economy;

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

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

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

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

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

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

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

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

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

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

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

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

Our executive officers, directors and principal stockholders and their affiliates beneficially own in the aggregate, shares representing approximately 36.89% of our capital stock as of December 31, 2015. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of ownership control may:

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

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

As of December 31, 2015, we had federal net operating loss, or NOL, carryforwards of $278 million and state NOL carryforwards of $138 million available to reduce future taxable income. These federal and state NOL carryforwards will begin to expire in 2020, if not utilized. Utilization of these NOL and tax credit carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and comparable provisions of state, local and foreign tax laws due to changes in ownership of our company that have occurred previously or that could occur in the future. We have completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation. The results of this study indicate that we experienced ownership changes, as defined by Section 382 of the Code. We have not identified NOLs that, as a result of these limitations, will expire unused. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we generate taxable income, our ability to use our pre-change NOL and tax credits carryforwards to reduce U.S. federal and state taxable income may be subject to further limitations, which could result in increased future tax liability to us. All or a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

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

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

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

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

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

Our restated certificate of incorporation provides that, unless our board of directors otherwise determines, the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to our company or our stockholders, any action asserting a claim against us or any of our directors or officers arising pursuant to any provision of the General Corporation Law of the State of Delaware, or any action asserting a claim against us or any of our directors or officers governed by the internal affairs doctrine. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors or officers, which may discourage such lawsuits against us and our directors and officers.

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

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

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

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

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

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

Our common stock began trading on the NASDAQ Global Select Market on July 1, 2015. As a public company, and particularly after we are no longer an EGC, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NASDAQ Global Market and other applicable securities rules and

regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we

will need to hire additional accounting, finance and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are currently evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal facilities consist of office space and manufacturing facilities in Bedford and Wilmington Massachusetts. We occupy approximately 90,000 square feet of office and manufacturing space in Bedford, Massachusetts under a lease that expires in April 2017. We occupy approximately 41,000 square feet of manufacturing space in Wilmington, Massachusetts under a lease that expires in April 2021. In 2015, we also occupied approximately 29,000 square feet of manufacturing space in Burlington, Massachusetts under a lease that expired in July 2015. We completed the transfer of our activities from the Burlington, Massachusetts facility to our facility in Wilmington, Massachusetts, in August 2015.

ITEM 3. LEGAL PROCEEDINGS

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

On September 3, 2015, a purported securities class action lawsuit was filed against us, our chief executive officer, and chief financial officer in the United States District Court for the District of Massachusetts. The complaint is brought on behalf of an alleged class of those who purchased our common stock in connection with our initial public offering or on the open market between July 1, 2015 and August 28, 2015, which we refer to as the class period. On November 2, 2015, two motions were filed on behalf of persons seeking to be named as lead plaintiff in the litigation. On November 10, 2015, the Court granted one petition, denied the other, and set a deadline for lead plaintiff to file a consolidated amended complaint, which the lead plaintiff filed on January 11, 2016. The consolidated amended complaint purports to allege claims arising under Sections 11 and 15 of the Securities Act of 1933, as amended, Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, including allegations that our stock was artificially inflated during the class period because the defendants allegedly made misrepresentations or did not make proper disclosures regarding our manufacturing process prior to our voluntary recall of specific serial numbers of patient-specific instrumentation for certain of our knee replacement product systems. Specifically, the complaint alleges that statements made during the class period were false and misleading because our manufacturing processes purportedly were flawed and, as a result of such flaws, a number of our knee replacement product systems were defective. The complaint seeks, among other relief, certification of the class, unspecified compensatory damages, interest, attorneys' fees, expert fees and other costs. We believe we have valid defenses to the claims in the lawsuit, and intend to defend ourselves vigorously. There can be no assurance, however, that we will be successful. An adverse outcome of the lawsuit could have a material adverse effect on our business, financial condition or results of operations. We are presently unable to predict the outcome of the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit. Additional complaints also may be filed against us and our directors and officers related to our voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems.

On October 21, 2015, a complaint for patent infringement was filed against us in the United States District Court for the District of Delaware by Orthopedic Innovations, Inc., which the complaint states is a subsidiary of Wi-LAN Technologies Inc. The complaint alleges that our iUni G2 and iDuo G2 partial knee replacement surgical techniques infringe one or more claims of United States Patent No. 6,575,980. The plaintiff seeks damages, including for willful infringement, attorney's fees, costs and a permanent injunction. We believe that none of our products or services infringes the plaintiff's patent. The plaintiff served the complaint on February 17, 2016. We intend to deny liability and to defend ourselves vigorously. There can be no assurance, however, that we will be successful. An adverse resolution of the lawsuit could have a material adverse effect on our business, financial condition or results of operations. We are presently unable to predict the outcome of the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit.

On February 29, 2016, we filed a lawsuit against Smith & Nephew, Inc. ("Smith & Nephew") in the United States District Court for the District of Massachusetts Eastern Division. The lawsuit alleges that Smith & Nephew's Visionaire® patient-specific instrumentation as well as the implants systems used in conjunction with the Visionaire instrumentation infringe eight of our patents, and it requests monetary damages for willful infringement and a permanent injunction.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol “CFMS” on the NASDAQ Global Select Market and has been publicly traded since July 1, 2015. Prior to this time, there was no public market for our common stock. The following table sets forth the high and low sales price of our common stock as reported on the NASDAQ Global Market for the periods indicated:

	High	Low
Year ended December 31, 2015:		
Third Quarter	$ 26.93	$ 13.33
Fourth Quarter	$ 23.62	$ 16.53

Holders of Our Common Stock

As of February 29, 2016, there were approximately 190 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in “nominee” or “street” name.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay any cash dividends to the holders of our common stock in the foreseeable future.

Stock Performance Graph

The following performance graph and related information shall not be deemed to be “soliciting material” or to be “filed” with the Securities and Exchange Commission, or SEC, for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, nor shall such information be incorporated by reference into any future filing under the Exchange Act or Securities Act of 1933, as amended, or the Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the performance of our common stock to the NASDAQ Composite Index and to the S&P 500 Health Care Equipment Index from July 1, 2015 (the first date that shares of our common stock were publicly traded) through December 31, 2015. The comparison assumes $100 was invested in our common stock and in each of the foregoing indices after the market closed on July 1, 2015, and it assumes reinvestment of dividends, if any. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

Recent Sales of Unregistered Securities

We did not sell any shares of our common stock, shares of our preferred stock or warrants to purchase shares of our stock, or grant any stock options or restricted stock awards, during the year ended December 31, 2015 that were not registered under the Securities Act and that have not otherwise been described in a Quarterly Report on Form 10-Q.

Use of Proceeds from Registered Securities

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

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

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

As of December 31, 2015, we have used approximately $43.5 million of the net proceeds from the offering as follows: $1.7 million to purchase and install capital equipment to expand our manufacturing capacity, approximately $20.9 million to expand and support our sales and marketing efforts, and approximately $8.6 million to fund research, development and clinical activities and approximately $12.3 million for general corporate and other purposes. We have not used any of the net proceeds from our IPO to make payments, directly or indirectly, to any director or officer of ours, to any of their associates, to persons owning 10% or more of our common stock or to any affiliates of ours. We have invested the remaining net proceeds from the offering in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities. There has been no material change in our planned use of the net proceeds from the initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on July 1, 2015.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read together with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report on Form 10-K. We have derived the statements of operations data for the years ended December 31, 2015 and 2014 from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We have derived the balance sheet data as of December 31, 2013 from our audited financial statements not included in this Annual Report on Form 10-K. Our historical results for any period are not necessarily indicative of results to be expected in any future period.

	Years ended December 31,		
(in thousands, except share and per share data)	2015	2014	2013
Consolidated statements of operations data:			
Revenue	$66,887	$48,186	$34,597
Cost of revenue	42,415	30,638	27,283
Gross profit	24,472	17,548	7,314
Operating expenses:			
Sales and marketing	40,245	31,103	26,149
Research and development	16,997	15,107	13,779
General and administrative	23,191	16,763	14,693
Total operating expenses	80,433	62,973	54,621
Loss from operations	(55,961)	(45,425)	(47,307)
Other income and expenses			
Interest income	138	104	89
Interest expense	(1,385)	(360)	(642)
Loss on extinguishment of debt	(205)	—	—
Other income (expense), net	208	—	—
Total other expenses	(1,244)	(256)	(553)
Loss before income taxes	(57,205)	(45,681)	(47,860)
Income tax provision	41	41	29
Net loss	$(57,246)	$(45,722)	$(47,889)
Net loss per share applicable to common stockholders—basic and diluted	$(2.60)	$(10.78)	$(11.98)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	21,993,066	4,239,564	3,996,867

	December 31,		
(in thousands)	2015	2014	2013
Consolidated balance sheet data:			
Cash and cash equivalents	$117,185	$37,900	$54,221
Working capital	133,004	45,036	54,277
Total assets	159,369	71,278	83,891
Long term debt, including current portion	478	10,620	3,111
Total stockholders' equity	141,212	49,827	68,960

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the ‘‘Risk Factors’’ section of this Annual Report on Form10-K, our actual results could differ materially from the results described, in or implied, by these forward-looking statements.

Overview

We are a medical technology company that uses our proprietary iFit Image-to-Implant technology platform to develop, manufacture and sell joint replacement implants that are individually sized and shaped, which we refer to as customized, to fit each patient’s unique anatomy. The worldwide market for joint replacement products is approximately $15 billion annually and growing, and we believe our iFit technology platform is applicable to all major joints in this market. We believe we are the only company offering a broad line of customized knee implants designed to restore the natural shape of a patient’s knee. We have sold a total of more than 40,000 knee implants in the United States and Europe. In clinical studies, iTotal CR, our cruciate-retaining total knee replacement implant and best-selling product, demonstrated superior clinical outcomes, including better function and greater patient satisfaction compared to traditional, off-the-shelf implants. In February 2015, we initiated the limited launch of iTotal PS, our posterior-stabilized total knee replacement implant which addresses the largest segment of the knee replacement market and we initiated the broad commercial launch of the iTotal PS in March 2016.

Our iFit technology platform comprises three key elements:

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

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

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

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

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

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

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Components of our results of operations

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

Revenue

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

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

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

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

We have accounted for the agreements with Wright Medical and MicroPort under ASC 605-25, Multiple-Element Arrangements and Staff Accounting Bulletin No. 104, Revenue Recognition (ASC 605). In accordance with ASC 605, we were required to identify and account for each of the separate units of accounting. We identified the relative selling price for each and then allocated the total consideration based on their relative values. In connection with these

agreements, in April 2015, we recognized in aggregate (i) back-owed royalties of $3.4 million as royalty revenue and (ii) the value attributable to the settlements of $0.2 million as other income. Additionally, we recognized an initial $5.1 million in aggregate as deferred royalty revenue, which is recognized as royalty revenue ratably through 2031. See “Note I — Deferred Revenue” to the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. The on-going royalty from MicroPort is recognized as royalty revenue upon receipt of payment.

On August 31, 2015, we announced a voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems. The recalled

products were manufactured and distributed from our Wilmington manufacturing facility between July 18, 2015 and August 28, 2015. We isolated the root cause to a step in our ethylene oxide sterilization process conducted by a vendor. We have since completed final testing and implemented corrective actions, and we resumed normal production in October 2015. In particular, our voluntary recall announced on August 31, 2015 has adversely affected our business and may continue to adversely affect our business in a number of ways, including through the financial impact from lost sales of the recalled products, reduction of our production capacity over the period of our investigation and resolution of the root cause of the recall, commercial disruption and damage to our reputation with orthopedic surgeons, consumers, healthcare providers, distributors and other business partners.

Cost of revenue

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

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

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

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

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

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

voluntary recall may depress our expected volume increases going forward as a result of potential damage to our reputation with consumers, healthcare providers, distributors and other business partners.

Operating expenses

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

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

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

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

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

Other income (expense), net

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

Income tax provision

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

Consolidated results of operations

Comparison of the years ended December 31, 2015 and 2014

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

Years Ended December 31,	2015 Amount	2015 As a% of Total Revenue	2014 Amount	2014 As a% of Total Revenue	2015 vs 2014 $ Change	2015 vs 2014 % Change
Revenue						
Product revenue	$62,791	94 %	$48,186	100 %	$14,605	30 %
Royalty	4,096	6	—	—	4,096	100
Total revenue	66,887	100	48,186	100	18,701	39
Cost of revenue	42,415	63	30,638	64	11,777	38
Gross profit	24,472	37	17,548	36	6,924	39
Operating expenses:						
Sales and marketing	40,245	60	31,103	65	9,142	29
Research and development	16,997	25	15,107	31	1,890	13
General and administrative	23,191	35	16,763	35	6,428	38
Total operating expenses	80,433	120	62,973	131	17,460	28
Loss from operations	(55,961)	(84)	(45,425)	(94)	(10,536)	(23)
Total other expenses	(1,244)	(2)	(256)	(1)	(988)	(386)
Loss before income taxes	(57,205)	(86)	(45,681)	(95)	(11,524)	(25)
Income tax provision	41	—	41	—	—	—
Net loss	$(57,246)	(86)%	$(45,722)	(95)%	$(11,524)	(25)%

Revenue. Product revenue was $62.8 million for the year ended December 31, 2015 compared to $48.2 million for the year ended December 31, 2014, an increase of $14.6 million or 30%, due principally to increased sales of our first primary total knee product, iTotal CR, as well as the addition on a limited basis of our iTotal PS product line.

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

Years Ended December 31,	2015 Amount	2015 As a % of Product Revenue	2014 Amount	2014 As a % of Product Revenue	2015 vs 2014 $ Change	2015 vs 2014 % Change
United States	$47,234	75 %	$34,332	71 %	$12,902	38 %
Germany	13,795	22	12,550	26	$1,245	10
Rest of world	1,762	3	1,304	3	458	35
Product revenue	$62,791	100 %	$48,186	100 %	$14,605	30 %

Product revenue in the United States was generated through our direct sales force and independent sales representatives. Product revenue outside the United States was generated through our direct sales force and distributors. The percentage of product revenue generated in the United States was 75% for the year ended December 31, 2015 compared to 71% for the year ended December 31, 2014. We believe the lower level of Germany

and rest of world product revenue as a percentage of product revenue in the year ended December 31, 2015 was due to the decline in foreign currency exchange rates for sales made in Germany and the United Kingdom and the increase in sales of iTotal PS in the United States.

In April 2015, we entered into a fully paid up, worldwide license agreement with Wright Medical for a single lump-sum payment by Wright Medical to us upon entering into the agreement. At this same time we also entered into a worldwide license agreement with MicroPort for a single lump-sum payment by MicroPort to us upon entering into the license agreement. Royalty revenue related to these agreements was $4.1 million for the year ended December 31, 2015.

Cost of revenue, gross profit and gross margin. Cost of revenue was $42.4 million for the year ended December 31, 2015 compared to $30.6 million for the year ended December 31, 2014, an increase of $11.8 million or 38%. The increase was due primarily to an increase in production and personnel costs associated with the increase in actual sales volume and, to a lesser extent, anticipated sales volume which was not achieved due to the recall announced in August 2015. Gross profit was $24.5 million for the year ended December 31, 2015 compared to $17.5 million for the year ended December 31, 2014, an increase of $6.9 million or 39%. Gross margin increased 100 basis points to 37% for the year ended December 31, 2015 from 36% for the year ended December 31, 2014. This increase in gross margin was driven primarily by the royalty revenue and higher sales volume during the year ended December 31, 2015 which was offset in part by the additional product costs, decrease in revenue due to the recall and foreign currency exchange rate changes.

Sales and marketing. Sales and marketing expense was $40.2 million for the year ended December 31, 2015 compared to $31.1 million for the year ended December 31, 2014, an increase of $9.1 million or 29%. The increase was due primarily to a $6.9 million increase in personnel costs as a result of our hiring of additional direct sales representatives and sales support and increases in commissions as a result of the increase in sales volume, and a $2.2 million increase in marketing and other expenses.

Research and development. Research and development expense was $17.0 million for the year ended December 31, 2015 compared to $15.1 million for the year ended December 31, 2014, an increase of $1.9 million or 13%. The increase was due primarily to a $1.0 million increase in personnel costs and a $0.9 million increase in revenue share expenses.

General and administrative. General and administrative expense was $23.2 million for the year ended December 31, 2015 compared to $16.8 million for the year ended December 31, 2014, an increase of $6.4 million or 38%. The increase was due primarily to a $2.2 million increase in personnel costs, a $1.1 million increase in consulting services expense and a $0.5 million increase in corporate director and officers insurance as a result of our initial public offering. Freight costs increased by $1.3 million as a result of our increase in sales volume and higher cost shipment methods used due to the winter storms during the first quarter of 2015 and the recall announced in August 2015. Facilities and office relocation costs increased $1.0 million to support our facility move. Additionally, there was a $0.3 million increase in bank fees related to the prepayment of our term loan, and a $1.0 million increase in various other expenses, offset in part by a decrease of $1.1 million in general and patent legal fees.

Other expense, net. Other expense, net was $1.2 million for the year ended December 31, 2015 compared to $0.3 million for the year ended December 31, 2014, an increase of $1.0 million, or 386%. The increase was primarily due to an increase of $0.3 million in interest expense associated with our long-term debt, an increase of $0.8 million related to the prepayment of our term loan, $0.2 million related to the termination of our revolving line, which was offset by $0.2 million in other income related to a gain on the royalty settlement from Wright and MicroPort.

Income taxes. Income tax provision was $41,000 for the year ended December 31, 2015 and 2014. We continue to generate losses for U.S. federal and state tax purposes and have net operating loss carryforwards creating a deferred tax asset. We maintain a full valuation allowance for deferred tax assets.

Comparison of the years ended December 31, 2014 and 2013

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

Years Ended December 31,	2014 Amount	2014 As a% of Total Revenue	2013 Amount	2013 As a% of Total Revenue	2014 vs 2013 $ Change	2014 vs 2013 % Change
Revenue						
Product revenue	$48,186	100 %	$34,597	100 %	$13,589	39 %
Royalty	—	—	—	—	—	100
Total revenue	48,186	100	34,597	100	13,589	39
Cost of revenue	30,638	64	27,283	79	3,355	12
Gross profit	17,548	36	7,314	21	10,234	140
Operating expenses:						
Sales and marketing	31,103	65	26,149	76	4,954	19
Research and development	15,107	31	13,779	40	1,328	10
General and administrative	16,763	35	14,693	42	2,070	14
Total operating expenses	62,973	131	54,621	158	8,352	15
Loss from operations	(45,425)	(94)	(47,307)	(137)	1,882	4
Total other expenses	(256)	(1)	(553)	(2)	297	54
Loss before income taxes	(45,681)	(95)	(47,860)	(138)	2,179	5
Income tax provision	41	—	29	—	12	41
Net loss	$(45,722)	(95)%	$(47,889)	(138)%	$2,167	5 %

Revenue. Revenue was $48.2 million for the year ended December 31, 2014 compared to $34.6 million for the year ended December 31, 2013, an increase of $13.6 million, or 39%, due principally to increased sales of our first primary total knee product, iTotal CR, and increased sales of our products generally outside the United States.

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

Years Ended December 31,	2014 Amount	2014 As a % of Product Revenue	2013 Amount	2013 As a % of Product Revenue	2014 vs 2013 $ Change	2014 vs 2013 % Change
United States	$34,332	71 %	$24,681	71 %	$9,651	39 %
Germany	12,550	26	9,128	26	$3,422	37
Rest of world	1,304	3	788	3	516	65
Product revenue	$48,186	100 %	$34,597	100 %	$13,589	39 %

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

Cost of revenue, gross profit and gross margin. Cost of revenue was $30.6 million for the year ended December 31, 2014 compared to $27.3 million for the year ended December 31, 2013, an increase of $3.3 million or 12%. The increase was due primarily to an increase in production costs and manufacturing supplies associated with the increase in sales volume. Gross profit increased $10.2 million, or 140%, to $17.5 million, in 2014 as compared to $7.3 million

in 2013 due to higher sales volume, while our gross margin increased 1,500 basis points to 36% from 21% in 2013. This increase in gross margin was driven by additional volume related material discounts and decreased costs of iJigs and tibial components as a result of the increasing vertical integration of

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

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

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

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

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

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

Liquidity, capital resources and plan of operations

Sources of liquidity and funding requirements

From our inception in June 2004 through the year ended December 31, 2015, we have financed our operations through private placements of preferred stock, our initial public offering, or IPO, bank debt and convertible debt financings, equipment purchase loans and product revenue beginning in 2007. Our product revenue has continued to grow from year-to-year; however, we have not yet attained profitability and continue to incur operating losses. As of December 31, 2015, we had an accumulated deficit of $325 million.

From 2004 through the year ended December 31, 2015, we have raised an aggregate of $330 million from the sale of preferred stock and the exercise of preferred stock warrants and common stock warrants and options.

In June 2011, we entered into a $1.4 million secured term loan facility with the Massachusetts Development Financing Agency, referred to as the MDFA facility, to finance equipment purchases, of which $0.5 million was outstanding as of December 31, 2015 and $0.8 million was outstanding as of December 31, 2014. We are scheduled to make monthly interest and principal payments for the MDFA facility through July 2017. For further information regarding this facility, see “Note K—Debts and Notes Payable—$1.4 million term loan—Massachusetts Development Finance Agency” in th financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

In May 2014, we made the final payment on a $15 million term loan facility with Western Technology Investment under which we originally borrowed $10 million in 2011. For further information regarding this facility, see “Note K—Debts and Notes Payable—$15 million term loan—WTI Term Loan II” in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

In November 2014, we entered into a senior secured $25 million loan and security agreement with Silicon Valley Bank and Oxford Finance, LLC, referred to as the 2014 Secured Loan Agreement consisting of a revolving line of credit issued by Silicon Valley Bank, or the Revolving Line, of up to $5 million and commitments for two term

loans issued jointly by Silicon Valley Bank and Oxford Finance, LLC, or the SVB/Oxford Term Loans, of $10 million each. In November 2014, in connection with our entry into the 2014 Secured Loan Agreement, we drew down the first $10 million term loan, referred to as the SVB/Oxford Term Loan A. In September 2015, we voluntarily prepaid the SVB/ Oxford Term Loan A and terminated the Company's right to draw down the SVB/Oxford Term Loans and any security interest in favor of Oxford Finance, LLC. In December 2015, we also terminated the Revolving Line. For further information regarding this facility, see "Note K—Debts and Notes Payable—2014 Secured Loan Agreement" in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

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

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

- expansion of our sales and marketing efforts;
- expansion of our manufacturing capacity;
- funding research, development and clinical activities related to our existing products and product platform, including iFit design software and product support;
- funding research, development and clinical activities related to new products that we may develop, including other joint replacement products;
- pursuing and maintaining appropriate regulatory clearances and approvals for our existing products and any new products that we may develop; and
- preparing, filing and prosecuting patent applications, and maintaining and enforcing our intellectual property rights and position.

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

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

We may need to engage in additional equity or debt financings to secure additional funds. We may not be able to obtain additional financing on terms favorable to us, or at all. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted. The terms of these future or

debt securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders or involve negative covenants that restrict our ability to take specific actions, such as incurring additional debt or making capital expenditures.

At December 31, 2015, we had cash and cash equivalents of $117.2 million and $0.6 million in restricted cash allocated to lease deposits. Based on our current operating plan, we expect that our existing cash and cash equivalents as of December 31, 2015 and anticipated revenue from operations, including from projected sales of our products, will enable us to fund our operating expenses and capital expenditure requirements and pay our debt

service as it becomes due for at least the next 12 months. We have based this expectation on assumptions that may prove to be wrong, such as the revenue that we expect to generate from the sale of our products and the gross profit we expect to generate from those revenues, and we could use our capital resources sooner than we expect.

Cash flows

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

	Years Ended December 31,			
	2015	2014	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$(54,450)	$(43,539)	$(10,911)	(25)%
Investing activities	(806)	(1,506)	700	46
Financing activities	134,565	29,337	105,228	359
Effect of exchange rate on cash	(24)	(613)	589	96
Total	$79,285	$(16,321)	$95,606	586 %

Net cash used in operating activities. Net cash used in operating activities was $54.5 million for the year ended December 31, 2015 and $43.5 million for the year ended December 31, 2014, an increase of $10.9 million. These amounts primarily reflect net losses of $57.2 million for the year ended December 31, 2015 and $45.7 million for the year ended December 31, 2014. The net cash used in operating activities for the year ended December 31, 2015 was affected by changes in our operating assets and liabilities, including an increase in deferred royalty revenue of $4.9 million, an increase in non-cash stock-based compensation and depreciation totaling $2.0 million, offset by a decrease of $0.1 million in accounts payable and accrued liabilities, an increase in our accounts receivable of $3.2 million, an increase in our inventory of $2.8 million, and an increase in our outstanding prepaid and other assets of $0.7 million.

Net cash used in investing activities. Net cash used in investing activities was $0.8 million for the year ended December 31, 2015 and $1.5 million for the year ended December 31, 2014, a decrease of $0.7 million. These amounts primarily reflect a decrease of $2.7 million in restricted cash balances offset by an increase of $2.0 million in cash used for purchases of property and equipment. We anticipate that the amount of cash used in investing activities will increase in 2016 as we purchase additional property and equipment to manufacture more components in our own facility.

Net cash provided by financing activities. Net cash provided by financing activities was $134.6 million for the year ended December 31, 2015 and $29.3 million for the year ended December 31, 2014, an increase of $105.2 million. The increase was due to a $122.6 million increase in net proceeds from the issuance of common and preferred stock, which was offset by a $10.0 million decrease in debt proceeds and a $7.9 million increase in debt payments primarily related to the prepayment of the SVB/Oxford Term Loan A.

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

	Years Ended December 31,			
	2014	2013	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$(43,539)	$(46,826)	$3,287	7 %
Investing activities	(1,506)	(8,457)	6,951	82
Financing activities	29,337	69,603	(40,266)	(58)

Effect of exchange rate on cash	(613)	167	(780)	(467)%
Total	$(16,321)	$14,487	$(30,808)	(213)%

Net cash used in operating activities. Net cash used in operating activities was $43.5 million for the year ended December 31, 2014 and $46.8 million for the year ended December 31, 2013, primarily reflecting the net losses during the periods of $45.7 million for the year ended December 31, 2014 and $47.9 million for the year

ended December 31, 2013. The net cash used in operating activities for the year ended December 31, 2014 was affected by changes in our operating assets and liabilities, including an increase of $2.1 million in accounts payable and accrued liabilities as well as non-cash stock-based compensation and depreciation totaling $4.6 million, which were offset in part by an increase in our outstanding prepaid and other assets of $0.3 million, an increase in our accounts receivable of $2.9 million and an increase in our inventory of $1.1 million. The net cash used in operating activities for the year ended December 31, 2013 was affected by changes in our operating assets and liabilities, including non-cash stock-based compensation and depreciation totaling $3.8 million, which was offset in part by an increase in our accounts receivable of $2.1 million and an increase in our inventory of $1.4 million.

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

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

Contractual obligations and commitments

The following table summarizes our contractual obligations as of the year ended December 31, 2015 (in thousands):

	Payment Due by Period				
Contractual Obligations	Total	Less than 1 year	Years 2 to 3	Years 4 to 5	After 5 years
Senior secured debt (1)	$481	$299	$182	$—	$—
Operating lease obligations - real estate (2)	4,021	1,615	1,153	1,253	—
Other (3)	3,077	609	1,043	750	675
Total (4)	$7,579	$2,523	$2,378	$2,003	$675

(1) Represents amounts payable under the MDFA facility.

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

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

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

Revenue share agreement

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

expiration or termination of the agreement, but in some cases expire on a product-by-product basis or expiration of the last to expire of our patents for which the advisor is a named inventor that claims the applicable product.

Philipp Lang, M.D., our Chief Executive Officer, joined our scientific advisory board in 2004 prior to becoming an employee. We first entered into a revenue share agreement with Dr. Lang in 2008 when he became our Chief Executive Officer. In 2011, we entered into an amended and restated revenue share agreement with Dr. Lang. Under this agreement, the specified percentage of our net revenues payable to Dr. Lang ranges from 0.875% to 1.33% and applies to all of our current and planned products, including our iUni, iDuo, iTotal Cr, iTotal PS and iTotal Hip products, as well as certain other knee, hip and shoulder replacement products and related instrumentation we may develop in the future. Our payment obligations under this agreement expire on a product-by-product basis on the last to expire of our patents on which Dr. Lang is named as an inventor that claim the applicable product. These payment obligations survive termination of Dr. Lang's employment with us. We incurred revenue share expense paid to Dr. Lang of $0.8 million, $0.6 million and $0.4 million for the years ended December 31, 2015, 2014 and 2013, respectively.

The aggregate revenue share percentage of net revenue from our currently marketed knee replacement products, including percentages under all of our scientific advisory board and Chief Executive Officer revenue share agreements, ranges, depending on the particular product, from 3.4% to 5.8%. We incurred aggregate revenue share expense, included in research and development, including all amounts payable under our scientific advisory board and Chief Executive Officer revenue share agreements of $3.2 million during the year ended December 31, 2015, representing 5.0% of product revenue, $2.3 million during the year ended December 31, 2014, representing 4.7% of product revenue, and $1.4 million during the year ended December 31, 2013, representing 4% of product revenue. For further information, see "Note J—Commitments and Contingencies —Revenue Share Agreements" or "Note L—Related Party Transactions —Revenue Share Agreement" in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

Segment information

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

Off-balance sheet arrangements

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

Critical accounting policies and significant judgments and use of estimates

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

Revenue recognition

We generate revenue from the sale of customized implants and instruments to medical facilities through the use of a combination of direct sales personnel, independent sales representatives and distributors.

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

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

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

Accounts receivable and allowance for doubtful accounts

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

Inventories

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

Intangibles and other long-lived assets

Intangible assets consist of developed technology and other intellectual property rights licensed from ImaTx as part of the spin-out transaction in 2004. Intangible assets are carried at cost less accumulated amortization. We test impairment of long-lived assets when events or changes in circumstances indicate that the assets might be impaired. For assets with determinable useful lives, amortization is computed using the straight-line method over the estimated economic lives of the respective intangible assets.

Furthermore, periodically we assess whether long-lived assets, including intangible assets, should be tested for recoverability whenever events or circumstances indicate that their carrying value may not be recoverable. The amount of impairment, if any, is measured based on fair value, which is determined using estimated undiscounted cash flows to be generated from such assets or group of assets. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, the Company may be required to record impairment charges. During the years ended December 31, 2015, 2014 or 2013, no such impairment charges were recognized.

Stock-based compensation

We account for stock-based compensation in accordance with ASC 718, Stock Based Compensation. ASC 718 requires all stock-based payments to employees and consultants, including grants of stock options, to be recognized in the consolidated statements of operations based on their fair values. We use the Black-Scholes option pricing model to determine the weighted-average fair value of options granted and recognizes the compensation expense of stock-based awards on a straight-line basis over the vesting period of the award.

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

The stock price for option grants are set by our board of directors and, prior to our IPO in July 2015, were based upon guidance set forth by the American Institute of Certified Public Accountants, or AICPA, in its Technical Practice Aid, “Valuation of Privately Held Company Equity Securities Issued as Compensation”. To that end, the board considered a number of factors in determining the option price, including: (1) past sales of our convertible preferred stock, and the rights, preferences and privileges of the Company stock, (2) obtaining FDA 510(k) clearance, and (3) achievement of budgeted results. See “Note M—Stockholders’ Equity” to the consolidated financial statements appearing in this Annual Report on Form 10-K for a summary of the stock option activity under our stock-based compensation plan.

JOBS Act accounting election

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

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-9, “Revenue from Contracts with Customers (Topic 606)” ("ASU 2014-9"). ASU 2014-9 outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new guidance was to be effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2017; early adoption was permitted for annual reporting periods beginning after December 15, 2016, including interim reporting periods within those annual periods. Companies have the option of using either a full retrospective or a modified retrospective approach to adopt the guidance. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of the guidance contained in ASU 2014-9 by one year. Thus, the guidance is effective for us commencing in the first quarter of 2018. We are currently evaluating the impact of this pronouncement on its consolidated financial statements and expect to adopt this pronouncement commencing in the first quarter of 2018.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40)—Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern ("ASU 2014-15"). This newly issued accounting standard provides guidance about management’s responsibility to evaluate whether there is a “substantial doubt” about an entity’s ability to continue as a going concern and to provide related footnote disclosures. The defined term “substantial doubt” requires an evaluation of every reporting period including interim periods, provides principles for considering the mitigating effect of management’s plans, requires certain disclosures when substantial doubt is alleviated as a result of consideration of management’s plans, requires an express statement and other disclosures when substantial doubt is not alleviated, and requires an assessment for a period of one year after the date that the financial statements are issued or available to be issued. The amendments in ASU 2014-15 are effective for annual periods beginning after December 15, 2016 and interim periods within those reporting periods. Earlier adoption is permitted. We are currently evaluating the impact of this pronouncement on its consolidated financial statements and expects to adopt this pronouncement commencing in the first quarter of 2017.

In April 2015, the FASB issued ASU No. 2015-3, “Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs” ("ASU 2015-3"), which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability, consistent with debt discounts. ASU 2015-3 applies to all business entities and is effective for public business entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted. We do not expect that the adoption of ASU 2015-3 will have a material effect on our

consolidated financial statements and expect to adopt this pronouncement commencing the first quarter of in 2016.

In April 2015, the FASB issued ASU No. 2015-5, “Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement” (“ASU 2015-5”), which provides guidance to clarify the customer’s accounting for fees paid in a cloud computing arrangement. This guidance is effective for annual periods and interim reporting periods of public entities beginning after

December 15, 2015. We do not expect that the adoption of ASU 2015-5 will have a material effect on its consolidated financial statements and expect to adopt this pronouncement commencing in the first quarter of 2016.

In November 2015, the FASB issued ASU No. 2015-17, "'Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes" ("ASU 2015-17"), which eliminates the current requirement for organizations to present deferred tax liabilities and assets as current and noncurrent in a classified balance sheet. Instead, organizations will be required to classify all deferred tax assets and liabilities as noncurrent. This guidance is effective for public companies financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. We do not expect that the adoption of ASU 2015-17 will have a material effect on our consolidated financial statements and expect to adopt this pronouncement commencing in the first quarter of 2017.

In January 2016, the FASB issued ASU No. 2016-01, "Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities", which requires, among other things:

- equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income;
- public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes;
- separate presentation of financial assets and financial liabilities by measurement category and form of financial asset (i.e., securities or loans and receivables); and
- eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost.

This guidance is effective for public companies for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. We are currently evaluating the impact of this pronouncement on our consolidated financial statements and expect to adopt this pronouncement commencing in the first quarter of 2018.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)." This ASU is a comprehensive new leases standard that amends various aspects of existing guidance for leases and requires additional disclosures about leasing arrangements. It will require companies to recognize lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. Topic 842 retains a distinction between finance leases and operating leases. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous leases guidance. The ASU is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years; earlier adoption is permitted. In the financial statements in which the ASU is first applied, leases shall be measured and recognized at the beginning of the earliest comparative period presented with an adjustment to equity. Practical expedients are available for election as a package and if applied consistently to all leases. We are currently evaluating the impact of this pronouncement on our consolidated financial statements and expect to adopt this pronouncement commencing in the first quarter of 2019.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest rate risk

We are exposed to limited market risk related to fluctuation interest rates and market prices. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of December 31, 2015 we had cash and cash equivalents of $117 million consisting of demand deposits and money market accounts on deposit with certain financial institutions. We had $2.1 million as of December 31, 2015 and $1.2 million as of December 31, 2014 held in foreign bank accounts that were not federally insured. A hypothetical 100 basis point change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Foreign currency exchange risk

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies could adversely affect our financial results. Approximately 25% of our product revenue for the year ended December 31, 2015 and 29% of our product revenue for the years ended December 31, 2014 and 2013 were denominated in foreign currencies. We expect that foreign currencies will continue to represent a similarly significant percentage of our net sales in the future. Costs of revenue related to these sales are primarily denominated in U.S. dollars; however, operating costs, including sales and marketing and general and administrative expense, related to these sales are largely denominated in the same currencies as the sales, thereby partially limiting our transaction risk exposure. Additionally, fluctuations in foreign currency exchange rates may cause us to recognize transaction gains and losses in our statement of operations. To date, foreign currency transaction realized gains and losses have not been material to our consolidated financial statements, and we have not engaged in any foreign currency hedging transactions. As our international operations grow, we will continue to reassess our approach to managing the risks relating to fluctuations in currency rates. A 10% increase or decrease in foreign currency exchange rates would have resulted in additional income or expense of $0.5 million for the years ended December 31, 2015 and December 31, 2014, and $0.3 million for the year ended December 31, 2013.

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
ConforMIS, Inc.

We have audited the accompanying consolidated balance sheets of ConforMIS, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ConforMIS, Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

/s/ GRANT THORNTON LLP
Boston, Massachusetts
March 24, 2016

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2015	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	$117,185	$37,900
Accounts receivable, net	14,867	9,119
Inventories	11,520	7,691
Prepaid expenses and other current assets	2,451	1,158
Total current assets	146,023	55,868
Property and equipment, net	10,966	8,696
Other Assets		
Restricted cash	600	4,438
Intangible assets, net	995	1,243
Goodwill	753	753
Other long-term assets	32	280
Total assets	$159,369	$71,278
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$4,718	$3,618
Accrued expenses	7,811	6,942
Deferred revenue	305	—
Current portion of long-term debt	295	272
Total current liabilities	13,129	10,832
Other long-term liabilities	220	271
Deferred revenue	4,625	—
Long-term debt	183	10,348
Total liabilities	18,157	21,451
Commitments and contingencies	—	—
Stockholders’ equity		
Convertible preferred stock, $0.00001 par value: Authorized: Zero and 53,496,241 shares authorized at December 31, 2015 and December 31, 2014, respectively, zero and 50,985,652 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively; (aggregate liquidation value of $0 and $352,626 at December 31, 2015 and December 31, 2014, respectively)	—	—
Preferred stock, $0.00001 par value: Authorized: 5,000,000 and zero shares authorized at December 31, 2015 and December 31, 2014, respectively; no shares issued and outstanding as of December 31, 2015 and December 31, 2014	—	—
Common stock, $0.00001 par value: Authorized: 200,000,000 and 80,000,000 shares authorized at December 31, 2015 and December 31, 2014, respectively; 41,110,127 and 4,286,164 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	—	—

Additional paid-in capital	467,075	318,420
Accumulated deficit	(325,342)	(268,096)
Accumulated other comprehensive loss	(521)	(497)
Total stockholders' equity	141,212	49,827
Total liabilities and stockholders' equity	$159,369	$71,278

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

CONFORMIS, INC. AND SUBSIDIARIES

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

	Years Ended December 31,		
	2015	2014	2013
Revenue			
Product	$62,791	$48,186	$34,597
Royalty	4,096	—	—
Total revenue	66,887	48,186	34,597
Cost of revenue	42,415	30,638	27,283
Gross profit	24,472	17,548	7,314
Operating expenses			
Sales and marketing	40,245	31,103	26,149
Research and development	16,997	15,107	13,779
General and administrative	23,191	16,763	14,693
Total operating expenses	80,433	62,973	54,621
Loss from operations	(55,961)	(45,425)	(47,307)
Other income and expenses			
Interest income	138	104	89
Interest expense	(1,385)	(360)	(642)
Loss on extinguishment of debt	(205)	—	—
Other income (expense)	208	—	—
Total other expenses	(1,244)	(256)	(553)
Loss before income taxes	(57,205)	(45,681)	(47,860)
Income tax provision	41	41	29
Net loss	$(57,246)	$(45,722)	$(47,889)
Net loss per share - basic and diluted	$(2.60)	$(10.78)	$(11.98)
Weighted average common shares outstanding - basic and diluted	21,993,066	4,239,564	3,996,867

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

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss
(in thousands)

	Years Ended December 31,		
	2015	2014	2013
Net loss	$(57,246)	$(45,722)	$(47,889)
Other comprehensive income (loss)			
Foreign currency translation adjustments	(24)	(613)	167
Comprehensive loss	$(57,270)	$(46,335)	$(47,722)

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

CONFORMIS, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity
(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock					
	Shares	Par Value	Shares	Par Value	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance, December 31, 2012	38,503,591	$ —	3,827,267	$ —	$217,631	$ (174,485)	$ (51)	$43,095
Issuance of common stock—option exercise			333,911	—	521			521
Issuance of Series E-1 preferred stock	5,801,250	—			49,465			49,465
Issuance of warrants to purchase Series E-1 preferred stock					1,533			1,533
Issuance costs of Series E-1 preferred stock					(5,257)			(5,257)
Issuance of Series E-2 preferred stock	3,506,875	—			25,000			25,000
Issuance costs of Series E-2 preferred stock					(12)			(12)
Compensation expense related to issued stock options					2,337			2,337
Net loss						(47,889)		(47,889)
Other comprehensive income							167	167
Balance, December 31, 2013	47,811,716	—	4,161,178	—	291,218	(222,374)	116	68,960
Issuance of common stock—option exercise			124,986	—	121			121
Issuance of Series D preferred stock—warrant exercise	367,456	—			2,205			2,205
Issuance of Series E-1 preferred stock	2,806,480	—			22,452			22,452
Issuance costs of Series E-1 preferred stock					(302)			(302)
Issuance of Series E-1 and E-2 preferred stock warrants					42			42
Issuance costs of common stock warrants					134			134
Compensation expense related to issued stock options					2,550			2,550
Net loss						(45,722)		(45,722)

Other comprehensive income							(613)	(613)
Balance, December 31, 2014	50,985,652	—	4,286,164	—	318,420	(268,096)	(497)	49,827
Issuance of common stock—option exercise			383,458	—	806			806
Issuance of common stock—restricted stock			174,530	—	—			—
Issuance of common stock—warrant exercise			11,734	—	18			18
Issuance of common stock—initial public offering			10,350,000	—	139,766			139,766
Issuance of common stock—preferred stock conversion to common stock	(51,808,561)	—	25,904,241	—	—			—
Issuance of Series D preferred stock—warrant exercise	321,854	—			450			450
Issuance of Series E-1 preferred stock—warrant exercise	300,059	—			2,400			2,400
Issuance of Series E-2 preferred stock—warrant exercise	200,996	—			1,608			1,608
Compensation expense related to issued stock options					3,607			3,607
Net loss						(57,246)		(57,246)
Other comprehensive income							(24)	(24)
Balance, December 31, 2015	—	$ —	41,110,127	$ —	$467,075	$ (325,342)	$ (521)	$141,212

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

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2015	2014	2013
Cash flows from operating activities			
Net loss	$(57,246)	$(45,722)	$(47,889)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation and amortization expense	2,619	2,080	1,882
Amortization of debt discount	135	24	151
Stock-based compensation expense	3,607	2,550	2,337
Provision for bad debts on trade receivables	359	6	14
Disposal of long term assets	2	44	—
Loss on extinguishment of debt	205	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(6,107)	(2,929)	(2,089)
Inventories	(3,829)	(1,071)	(1,424)
Prepaid expenses and other assets	(1,045)	(332)	47
Accounts payable and accrued liabilities	1,969	2,075	117
Deferred royalty revenue	4,932	—	—
Other long-term liabilities	(51)	(264)	28
Net cash used in operating activities	(54,450)	(43,539)	(46,826)
Cash flows from investing activities:			
Acquisition of property and equipment	(4,643)	(2,614)	(4,112)
Decrease (increase) in restricted cash	3,837	1,108	(4,345)
Net cash used in investing activities	(806)	(1,506)	(8,457)
Cash flows from financing activities:			
Net proceeds from issuance of preferred stock	—	21,598	73,578
Proceeds from exercise of common stock options	806	121	521
Proceeds from exercise of common stock warrant	18	—	—
Proceeds from exercise of preferred stock warrant	4,458	—	—
Proceeds from issuance of debt	—	10,000	—
Payments on notes payable	(10,278)	(2,382)	(4,496)
Payment on extinguishment of debt	(205)	—	—
Net proceeds from issuance of common stock	139,766	—	—
Net cash provided by financing activities	134,565	29,337	69,603
Foreign exchange effect on cash and cash equivalents	(24)	(613)	167
(Decrease) increase in cash and cash equivalents	79,285	(16,321)	14,487
Cash and cash equivalents, beginning of period	37,900	54,221	39,734
Cash and cash equivalents, end of period	$117,185	$37,900	$54,221
Supplemental information:			
Cash paid for income taxes	$187	$156	$123
Cash paid for interest	1,284	162	560
Non cash investing and financing activities			

Issuances of Series E-1 preferred stock warrants	—	177	1,533

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

CONFORMIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note A—Organization and Basis of Presentation

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

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

Liquidity and operations

Since the Company's inception in June 2004, it has financed its operations through private placements of preferred stock, its initial public offering in July 2015, bank debt and convertible debt financings, equipment purchase loans, and, beginning in 2007, product revenue. The Company's product revenue has continued to grow from year-to-year; however, it has not yet attained profitability and continues to incur operating losses. At December 31, 2015, the Company had an accumulated deficit of $325.3 million.

In November 2014, the Company entered into a senior secured $25 million loan and security agreement with Silicon Valley Bank and Oxford Finance, LLC (the "2014 Secured Loan Agreement"), consisting of a revolving line of credit, issued by Silicon Valley Bank (the "Revolving Line") of up to $5 million and commitments for two term loans issued jointly by Silicon Valley Bank and Oxford Finance, LLC (the "SVB/Oxford Term Loans") of $10 million each. In November 2014, in connection with the Company's entry into the 2014 Secured Loan Agreement, the Company drew down the first $10 million term loan (the "SVB/Oxford Term Loan A"). Under the 2014 Secured Loan Agreement, the Company could draw down a second $10 million term loan on or prior to November 7, 2015 upon meeting certain conditions. In September 2015, the Company voluntarily prepaid the SVB/Oxford Term Loan A in full and terminated the Company's right to draw down the SVB/Oxford Term Loans and any security interest in favor of Oxford Finance, LLC. In December 2015, the Company also terminated the Revolving Line. For further information regarding this facility, see "Note K—Debt and Notes Payable—2014 Secured Loan Agreement" below. The Company expects to incur substantial expenditures in the foreseeable future in connection with the continued expansion of its business.

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

At December 31, 2015, the Company had cash and cash equivalents and investments of $117.2 million and $0.6 million in restricted cash allocated to lease deposits. At December 31, 2014, the Company had cash and cash equivalents and investments of $37.9 million and $4.4 million in restricted cash allocated to lease deposits and funding for its Asia strategy. See "Note L—Related Party Transactions" for a description of the Asia strategy.

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

by the Company. The Company's common stock began trading on the NASDAQ Global Select Market on July 1, 2015.

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

- the issuance of the 10,350,000 shares of the Company's common stock;
- the automatic conversion of all outstanding shares of the Company's preferred stock into 25,527,505 shares of common stock;
- the issuance of 380,902 shares of the Company's common stock upon the exercise or exchange of warrants to purchase the Company's common stock, which consisted of warrants to purchase:
  - 4,166 shares of the Company's common stock;
  - 252,429 shares of the Company's Series D preferred stock;
  - 300,059 shares of the Company's Series E-1 preferred stock; and
  - 200,996 shares of the Company's Series E-2 preferred stock;

- the issuance of a warrant to purchase 142,857 shares of the Company's common stock at an exercise price of $7.00 per share in replacement of a warrant to purchase 285,714 shares of the Company's Series C preferred stock at an exercise price of $3.50 per share;
- the conversion of a warrant to purchase 160,000 shares of the Company's Series D preferred stock at an exercise price of $6.00 per share into a warrant to purchase 80,000 shares of common stock at an exercise price of $12.00 per share; and
- the expiration of warrants to purchase 482,964 shares of the Company common stock, which consisted of warrants to purchase:
  - 64,217 shares of the Company's Series D preferred stock;
  - 215,807 shares of the Company's Series E-1 preferred stock; and
  - 202,940 shares of the Company's Series E-2 preferred stock.

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

At December 31, 2015, based on its current operating plan, the Company expects that its existing cash and cash equivalents as of December 31, 2015 and anticipated revenue from operations, including from projected sales of its products, will enable it to fund operating expenses and capital expenditure requirements and pay its debt service as it becomes due for at least the next 12 months.

In the event the Company's existing cash and available financing is not sufficient to fund its operations, the Company may need to engage in equity or debt financings to secure additional funds. The Company may not be able to obtain additional financing on terms favorable to the Company, or at all.

Basis of presentation and use of estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting periods. The most significant estimates used in these consolidated financial statements include the valuation of accounts receivable, inventory reserves, intangible valuation, equity instruments, impairment assessments, income tax reserves and related allowances, and the lives of property and equipment. Actual results may differ from those estimates.

Note B—Summary of Significant Accounting Policies

Concentrations of credit risk and other risks and uncertainties

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

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

For the years ended December 31, 2015, 2014 and 2013, no customer represented greater than 10% of revenue. There were no customers that represented greater than 10% of total gross receivable balance at December 31, 2015, December 31, 2014 or December 31, 2013.

Principles of consolidation

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

Cash and cash equivalents

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

The Company had $2.1 million as of December 31, 2015 and $1.2 million as of December 31, 2014 held in foreign bank accounts. In addition, the Company has recorded restricted cash of $0.6 million as of December 31, 2015 and $4.4 million as of December 31, 2014. Restricted cash consisted of $0.6 million as of December 31, 2015 and $0.8 million as of December 31, 2014 of security provided for a lease obligation, and $0 million as of December 31, 2015 and $3.6 million as of December 31, 2014 of proceeds received in connection with the sale of Series E-1 and E-2 preferred stock that was contractually restricted for use. See "Note L — Related Party Transactions" below.

Fair value of financial instruments

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

Accounts receivable and allowance for doubtful accounts

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

Inventories

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

factors in evaluating net realizable value.

Property and equipment

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

Intangibles and other long-lived assets

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

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

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

The amount of impairment, if any, is measured based on fair value, which is determined using estimated undiscounted cash flows to be generated from such assets or group of assets. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, the Company may be required to record impairment charges. During the years ended December 31, 2015, 2014 and 2013, no such impairment charges were recognized.

Goodwill

Goodwill relates to amounts that arose in connection with the acquisition of Imaging Therapeutics, Inc. (formerly known as Osteonet.com, renamed ImaTx, Inc.) in 2009. The Company tests goodwill at least annually for impairment, or more frequently when events or changes in circumstances indicate that the assets may be impaired. This impairment test is performed annually during the fourth quarter at the reporting unit level. Goodwill may be considered impaired if the carrying value of the reporting unit, including goodwill, exceeds the reporting unit’s fair value. The Company is comprised of one reporting unit. When testing goodwill for impairment, the Company primarily looks to the fair value of the reporting unit, which is typically estimated using a discounted cash flow approach, which requires the use of assumptions and judgments including estimates of future cash flows and the selection of discount rates. The goodwill recognized upon acquiring ImaTx is not deductible for tax purposes. In light of the voluntary product recall announced by the Company on August 31, 2015 of specific serial numbers of patient-specific instrumentation for the iUni, iDuo and iTotal systems, the Company assessed the potential for impairment of the goodwill carrying value and concluded that the recall did not affect the goodwill. During the years ended December 31, 2015, 2014 and 2013, there were no triggering events which would require an interim goodwill impairment assessment.

Revenue recognition

Product

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

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

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

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

Royalty

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

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

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

Shipping and handling costs

Amounts invoiced to customers for shipping and handling are classified as revenue. Shipping and handling costs incurred are included in general and administrative expense. Shipping and handling expense was $2.7 million, $1.4 million and $1.6 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Taxes collected from customers and remitted to government authorities

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

Research and development expense

The Company’s research and development costs consist of engineering, product development, quality assurance, clinical and regulatory expense. These costs primarily relate to employee compensation, including salary, benefits and stock-based compensation. The Company also incurs costs related to consulting fees,

materials and supplies, and marketing studies, including data management and associated travel expense. Research and development costs are expensed as incurred.

Advertising expense

Advertising costs are expensed as incurred, which are included in sales and marketing. Advertising expense was $0.3 million for the year ended December 31, 2015, $0.5 million for the year ended December 31, 2014 and $0.3 million for the year ended December 31, 2013.

Segment reporting

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

Comprehensive loss

At December 31, 2015, 2014 and 2013, accumulated other comprehensive loss consists of foreign currency translation adjustments.

Foreign currency translation and transactions

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

Income taxes

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

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

The tax benefit from an uncertain tax position is only recognized if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from these positions are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution.

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

Medical device excise tax

The Company is subject to the Health Care and Education Reconciliation Act of 2010 (the "Act"), which imposes a tax equal to 2.3% on the sales price of any taxable medical device by a medical device manufacturer, producer or importer of such device. Under the Act, a taxable medical device is any device defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, intended for humans, which includes an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which meets certain requirements. The Company incurred medical device excise tax expense of $0.8 million for the year ended December 31, 2015, $0.7 million for the year ended December 31, 2014 and 0.4 million for the year ended December 31, 2013, respectively. Medical device tax is included in general and administrative expense. The Consolidated Appropriations Act of 2016 includes a two-year moratorium on the medical device excise tax, which moratorium suspended taxes on the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016 and ending on December 31, 2017.

Stock-based compensation

The Company accounts for stock-based compensation in accordance with ASC 718, Stock Based Compensation. ASC 718 requires all stock-based payments to employees and consultants, including grants of stock options, to be recognized in the consolidated statements of operations based on their fair values. The Company uses the Black-Scholes option pricing model to determine the weighted-average fair value of options granted and recognizes the compensation expense of stock-based awards on a straight-line basis over the vesting period of the award.

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

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

Net loss per share

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

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

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

	Years Ended December 31,		
(in thousands, except share and per share data)	2015	2014	2013
Numerator:			
Numerator for basic and diluted loss per share:			
Net loss	$(57,246)	$(45,722)	$(47,889)
Denominator:			
Denominator for basic loss per share:			
Weighted average shares	21,993,066	4,239,564	3,996,867
Basic loss per share attributable to ConforMIS, Inc. stockholders	$(2.60)	$(10.78)	$(11.98)
Diluted loss per share attributable to ConforMIS, Inc. stockholders	$(2.60)	$(10.78)	$(11.98)

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

	Years Ended December 31,		
	2015	2014	2013
Series A Preferred	873,591	1,705,138	1,705,138
Series B Preferred	1,144,885	2,234,668	2,234,668
Series C Preferred	1,256,752	2,453,018	2,453,018
Series D Preferred	3,410,570	6,415,106	6,469,904
Series E-1 Preferred	3,748,578	6,530,429	4,352,976
Series E-2 Preferred	2,628,037	5,129,592	4,181,009
Series C Preferred Warrants	—	56,202	29,735
Series D Preferred Warrants	—	58,365	49,972
Series E-2 Preferred Warrants	—	5,883	25,555
Common stock warrants	303,931	25,733	1,708
Stock options	3,566,421	2,780,631	2,290,768
Total	16,932,765	27,394,765	23,794,451

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-9, “Revenue from Contracts with Customers (Topic 606)” ("ASU 2014-9"). ASU 2014-9 outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new guidance was to be effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2017; early adoption was permitted for annual reporting periods beginning after December 15, 2016, including interim reporting periods within those annual periods. Companies have the option of using either a full retrospective or a modified retrospective approach to adopt the guidance. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of the guidance contained in ASU 2014-9 by one year. Thus, the guidance is effective for us commencing in the first quarter of 2018. We are currently evaluating the impact of this pronouncement on its consolidated financial statements and expect to adopt this pronouncement commencing in the first quarter of 2018.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40)—Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern ("ASU 2014-15"). This newly issued accounting standard provides guidance about management’s responsibility to evaluate whether there is a

“substantial doubt” about an entity’s ability to continue as a going concern and to provide related footnote disclosures. The defined term “substantial doubt” requires an evaluation of every reporting

period including interim periods, provides principles for considering the mitigating effect of management's plans, requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, requires an express statement and other disclosures when substantial doubt is not alleviated, and requires an assessment for a period of one year after the date that the financial statements are issued or available to be issued. The amendments in ASU 2014-15 are effective for annual periods beginning after December 15, 2016 and interim periods within those reporting periods. Earlier adoption is permitted. We are currently evaluating the impact of this pronouncement on its consolidated financial statements and expects to adopt this pronouncement commencing in the first quarter of 2017.

In April 2015, the FASB issued ASU No. 2015-3, "Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs" ("ASU 2015-3"), which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability, consistent with debt discounts. ASU 2015-3 applies to all business entities and is effective for public business entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted. We do not expect that the adoption of ASU 2015-3 will have a material effect on our consolidated financial statements and expect to adopt this pronouncement commencing the first quarter of in 2016.

In April 2015, the FASB issued ASU No. 2015-5, "Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement" ("ASU 2015-5"), which provides guidance to clarify the customer's accounting for fees paid in a cloud computing arrangement. This guidance is effective for annual periods and interim reporting periods of public entities beginning after December 15, 2015. We do not expect that the adoption of ASU 2015-5 will have a material effect on its consolidated financial statements and expect to adopt this pronouncement commencing in the first quarter of 2016.

In November 2015, the FASB issued ASU No. 2015-17, "'Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes" ("ASU 2015-17"), which eliminates the current requirement for organizations to present deferred tax liabilities and assets as current and noncurrent in a classified balance sheet. Instead, organizations will be required to classify all deferred tax assets and liabilities as noncurrent. This guidance is effective for public companies financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. We do not expect that the adoption of ASU 2015-17 will have a material effect on our consolidated financial statements and expect to adopt this pronouncement commencing in the first quarter of 2017.

In January 2016, the FASB issued ASU No. 2016-01, "Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities", which requires, among other things:

- equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income;
- public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes;
- separate presentation of financial assets and financial liabilities by measurement category and form of financial asset (i.e., securities or loans and receivables); and
- eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost.

This guidance is effective for public companies for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. We are currently evaluating the impact of this pronouncement on our consolidated financial statements and expect to adopt this pronouncement commencing in the first quarter of 2018.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)." This ASU is a comprehensive new leases standard that amends various aspects of existing guidance for leases and requires additional disclosures about

leasing arrangements. It will require companies to recognize lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. Topic 842 retains a distinction between finance leases and operating leases. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous leases guidance. The ASU is effective for annual periods beginning after

December 15, 2018, including interim periods within those fiscal years; earlier adoption is permitted. In the financial statements in which the ASU is first applied, leases shall be measured and recognized at the beginning of the earliest comparative period presented with an adjustment to equity. Practical expedients are available for election as a package and if applied consistently to all leases. We are currently evaluating the impact of this pronouncement on our consolidated financial statements and expect to adopt this pronouncement commencing in the first quarter of 2019.

Note C—Fair Value Measurements

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

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

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

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

The only assets and liabilities subject to fair value measurement standards at December 31, 2015 and December 31, 2014 were money market funds that were cash equivalents based on Level 1 inputs. The values of these funds were $106.9 million as of December 31, 2015 and $30,000 as of December 31, 2014.

Note D—Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	December 31, 2015	December 31, 2014
Total receivables	$15,421	$9,281
Allowance for doubtful accounts and returns	(554)	(162)
Accounts receivable, net	$14,867	$9,119

Write-offs related to accounts receivable were approximately $88,000 for the year ended December 31, 2015, $70,000 for the year ended December 31, 2014 and $11,000 for year ended December 31, 2013.

Summary of allowance for doubtful accounts and returns activity was as follows:

	December 31, 2015	December 31, 2014
Beginning balance	(162)	(234)
Provision for bad debts on trade receivables	(359)	(6)
Other allowances	(121)	8
Accounts receivable write offs	88	70
Ending balance	$(554)	$(162)

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Note E—Inventories

Inventories consisted of the following (in thousands):

	December 31, 2015	December 31, 2014
Raw Material	$4,175	$3,311
Work in process	2,683	1,282
Finished goods	4,662	3,098
Total Inventories	$11,520	$7,691

At December 31, 2015, inventories included write-downs of $0.3 million and reserves of $37,000 for estimated surgery cancellations both related to units affected by the recall and sterilization capacity limitation.

Note F—Property and Equipment

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

	Estimated Useful Life (Years)	December 31, 2015	December 31, 2014
Equipment	5-7	$12,185	$9,598
Furniture and fixtures	5-7	391	362
Computer and software	3	5,229	3,725
Leasehold improvements	2-7	795	1,040
Total property and equipment		18,600	14,725
Accumulated depreciation		(7,634)	(6,029)
Property and equipment, net		$10,966	$8,696

Depreciation expense related to property and equipment was $2.4 million, $1.8 million and $1.6 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Note G—Intangible Assets

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

	Estimated Useful Life (Years)	December 31, 2015	December 31, 2014
Developed technology	10	$979	$979
Accumulated amortization		(582)	(485)
Developed technology, net		397	494
License agreements	10	1,508	1,508
Accumulated amortization		(910)	(759)
License technology, net		598	749
Intangible assets, net	10	$995	$1,243

The Company recognized amortization expense of $0.2 million in the years ended December 31, 2015, 2014 and 2013. The weighted-average remaining life of total amortizable intangible assets is 4 years for the developed technology and license agreements.

The estimated future aggregated amortization expense for intangible assets owned as of December 31, 2015 consisted of the following (in thousands):

	Amortization expense
2016	$249
2017	249
2018	249
2019	248
	$995

Note H—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2015	December 31, 2014
Accrued employee compensation	$3,585	$2,125
Deferred rent	213	277
Accrued legal expense	334	265
Accrued consulting expense	134	139
Accrued vendor charges	692	932
Accrued revenue share expense	932	727
Accrued patent settlement and license costs	500	750
Accrued clinical trial expense	302	211
Accrued other	1,119	1,516
	$7,811	$6,942

Note I — Deferred Revenue

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

Note J—Commitments and Contingencies

Operating Leases - Real Estate

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

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

were accelerated. In July 2015, the Company and the landlord of the Burlington facility agreed to a hold over for 30 days beyond the lease termination of July 31, 2015 through August 31, 2015. The Company also leases satellite facilities under short-term non-cancellable operating leases.

The future minimum rental payments under the Company's non-cancellable operating leases for real estate as of December 31, 2015 were as follows (in thousands):

Year	Minimum lease Payments
2016	$1,615
2017	789
2018	364
2019-2022	1,253
	$4,021

Rent expense of $1.6 million for the year ended December 31, 2015 and $1.5 million for the years ended December 31, 2014 and 2013 was charged to operations, respectively. The Company's operating lease agreements contain scheduled rent increases, which are being amortized over the terms of the agreements using the straight-line method. Deferred rent was $0.4 million as of December 31, 2015 and $0.5 million as of December 31, 2014. Deferred rent is included in accrued expenses and other long-term liabilities.

License and revenue share agreements

Settlement and patent license

In December 2014, the Company entered into a settlement and patent license agreement that grants ConforMIS a fully paid-up license to certain intellectual property and provides for the mutual release and absolute discharge of any and all claims in connection with the licensed patents and with suits filed by and against the parties to the agreement in exchange for $750,000 payable by the Company in two installments, wherein the first installment of $250,000 was paid in January of 2015 and the second installment of $500,000 was paid in January of 2016. The Company expensed the full amount of the consideration in 2014, included in general and administrative expense. The license continues until the expiration of the last patent.

Revenue share agreements

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

Philipp Lang, M.D., the Company's Chief Executive Officer, joined the Company's scientific advisory board in 2004 prior to becoming an employee. The Company first entered into a revenue share agreement with Dr. Lang in 2008 when he became the Company's Chief Executive Officer. In 2011, the Company entered into an amended and restated revenue share agreement with Dr. Lang. Under this agreement, the specified percentage of the Company's net revenues payable to Dr. Lang ranges from 0.875% to 1.33% and applies to all of the Company's current and planned products, including the Company's iUni, iDuo, iTotal Cr, iTotal PS and iTotal Hip products, as well as certain other knee, hip

and shoulder replacement products and related instrumentation the Company may develop in the future. The Company's payment obligations under this agreement expire on a product-by-product basis on the last to expire of the Company's patents on which Dr. Lang is named an inventor that claim the applicable product. These payment obligations survive termination of Dr. Lang's employment with the Company. The Company incurred revenue share expense paid to Dr. Lang of $0.8 million, $0.6 million and $0.4 million for the years ended December 31, 2015, 2014 and 2013, respectively.

The Company incurred aggregate revenue share expense including all amounts payable under the Company's scientific advisory board and Chief Executive Officer revenue share agreements of $3.2 million during the year ended December 31, 2015, representing 5.0% of product revenue, $2.3 million during the year ended December 31, 2014, representing 4.7% of product revenue, and $1.4 million during the year ended December 31, 2013, representing 4% of product revenue. Revenue share expense is included in research and development. See "Note L—Related Party Transactions" for further information regarding the Company's arrangement with its Chief Executive Officer.

Other obligations

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

The following table summarizes the Company's contractual obligations as of the year ended December 31, 2015 (in thousands):

	Payment Due by Period				
Contractual Obligations	Total	Less than 1 year	Years 2 to 3	Years 4 to 5	After 5 years
Senior secured debt (1)	$481	$299	$182	$—	$—
Operating lease obligations - real estate (2)	4,021	1,615	1,153	1,253	—
Other (3)	3,077	609	1,043	750	675
Total (4)	$7,579	$2,523	$2,378	$2,003	$675

(1) Represents amounts payable under the MDFA facility.

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

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

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

There have been no contingent liabilities requiring accrual at December 31, 2015 or December 31, 2014.

Legal proceedings

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

On September 3, 2015, a purported securities class action lawsuit was filed against the Company and certain of its officers in the United States District Court for the District of Massachusetts. The complaint is brought on behalf of an alleged class of those who purchased the Company's common stock in connection with its initial public offering or on the open market between July 1, 2015 and August 28, 2015, referred to as the class period. On November 2, 2015, two motions were filed on behalf of persons seeking to be named as lead plaintiff in the litigation. On November 10, 2015, the Court granted one petition, denied the other, and set a deadline for lead plaintiff to file a consolidated amended complaint, which the lead plaintiff filed on January 11, 2016. The consolidated amended complaint purports to allege claims arising under Sections 11 and 15 of the Securities Act of 1933, as amended, Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, including allegations that the

Company's stock was artificially inflated during the class period because the defendants allegedly made misrepresentations or did not make proper disclosures regarding the Company's manufacturing process prior to the voluntary recall of specific serial numbers of patient-specific

instrumentation for certain of its knee replacement product systems. Specifically, the complaint alleges that statements made during the class period were false and misleading because the manufacturing processes purportedly were flawed and, as a result of such flaws, a number of the Company's knee replacement product systems were defective. The complaint seeks, among other relief, certification of the class, unspecified compensatory damages, interest, attorneys' fees, expert fees and other costs. The Company believes that it has valid defenses to the claims in the lawsuit and intends to defend itself vigorously. There can be no assurance, however, that the Company will be successful. An adverse outcome of the lawsuit could have a material adverse effect on the Company's business, financial condition or results of operations. The Company is presently unable to predict the outcome of the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit. Additional complaints also may be filed against the Company and its directors and officers related to our voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems.

On October 21, 2015, a complaint for patent infringement was filed against the Company in the United States District Court for the District of Delaware by Orthopedic Innovations, Inc., which the complaint states is a subsidiary of Wi-LAN Technologies Inc. The complaint alleges that the Company's iUni G2 and iDuo G2 partial knee replacement surgical techniques infringe one or more claims of United States Patent No. 6,575,980. The plaintiff seeks damages, including for willful infringement, attorney's fees, costs and a permanent injunction. The Company believes that none of its products or services infringes the plaintiff's patent. The plaintiff served the complaint on February 17, 2016. The Company intends to deny liability and to defend itself vigorously. There can be no assurance, however, that the Company will be successful. An adverse resolution of the lawsuit could have a material adverse effect on the Company's business, financial condition or results of operations. The Company is presently unable to predict the outcome of the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit.

Legal costs associated with legal proceedings are accrued as incurred.

Indemnifications

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

Note K—Debt and Notes Payable

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

	December 31, 2015	December 31, 2014
Massachusetts Development Finance Agency	$481	$760
Oxford Finance, LLC	—	6,250
Silicon Valley Bank	—	3,750
	481	10,760
Less total discount	(3)	(140)
	478	10,620

Less current installments	295	272
Long-term debt, excluding current installments	$183	$10,348

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

	Principal Payment
2016	299
2017	182
Total	$481

2014 Secured Loan Agreement

On November 7, 2014, or the effective date, the Company entered into the 2014 Secured Loan Agreement consisting of the Revolving Line of up to $5 million (subject to availability under the borrowing base and satisfaction of other funding conditions), and commitments for the two $10 million SVB/Oxford Term Loans. At the time the Company entered into the 2014 Secured Loan Agreement, it borrowed the first $10 million term loan, or the SVB/Oxford Term Loan A, and issued the lenders warrants to purchase 33,481 shares of the Company's common stock. On September 8, 2015, the Company voluntarily prepaid the SVB/Oxford Term Loan A and terminated the Company's right to draw down the SVB/Oxford Term Loans and any security interest in the Company's assets in favor of Oxford Finance, LLC. At that time, the Company retained the Revolving Line with Silicon Valley Bank. On December 14, 2015, the Company terminated the Revolving Line.

Prior to the prepayment of the SVB/Oxford Term Loan A, the SVB/Oxford Term Loans each had a maturity date of November 1, 2019 (the "Term Loan Maturity Date"). The SVB/Oxford Term Loan A bore interest at a fixed rate of 7.25% per annum, which rate was determined as the prime rate on the original date of funding plus 4%. The Company never borrowed the SVB/Oxford Term Loan B. If the Company had borrowed the SVB/Oxford Term Loan B, such term loan would have accrued interest at a fixed per annum rate equal to the prime rate on the date of funding, plus 4%. Interest on each of the SVB/Oxford Term Loans was payable monthly in arrears. After an interest only period, the Company was required to make equal monthly payments of principal and interest, in arrears, for the remaining term until maturity. In addition to interest, the Company was obligated to make a final payment fee equal to the original principal amount of the applicable SVB/Oxford Term Loan, multiplied by 7%, which was paid by the Company with the term loan prepayment, and had been ratably expensed to interest while the loan was outstanding using the effective interest method. Further, the Company was required to pay a prepayment fee equal to 3% of the principal amount being prepaid. The Company was also eligible to borrow a second term loan in a principal amount of $10 million (the "SVB/Oxford Term Loan B"), on or prior to November 7, 2015, upon meeting certain conditions, including the Company being able to make certain agreed upon representations and warranties to the lenders and a determination by the lenders, in their sole discretion, that there had not been an occurrence of any material adverse change, as defined in the 2014 Secured Loan Agreement, or any material deviation from the annual financial projections provided by the Company and accepted by the lenders. In the event that the Company had borrowed the additional $10 million term loan, the Company would have been obligated to issue warrants to purchase an additional 33,481 shares of its common stock to the lenders under the 2014 Secured Loan Agreement. Also, immediately upon the occurrence and during the continuance of an event of default, all obligations outstanding under the agreement would have accrued interest at a fixed rate equal to the per annum rate that was otherwise applicable thereto plus 5%.

Prior to terminating the Revolving Line, the Company's ability to borrow under the Revolving Line was subject to a borrowing base, calculated as 85% (or such lower percent as Silicon Valley Bank may determine as prescribed in the 2014 Secured Loan Agreement) of eligible accounts receivable. Borrowings under the Revolving Line bore interest at a floating per annum rate equal to the prime rate. Interest on the Revolving Line was payable monthly. In addition to interest, the Company was obligated to pay a $250,000 fee for the Revolving Line payable in annual increments of $50,000. The Company was obligated to pay a termination fee of $50,000 when it elected to terminate the Revolving Line and the unpaid amount of the Revolving Line fee, which are included under other income and expenses. The Company's obligations under the Revolving Line were secured by a security interest over substantially all of the Company's and ImaTx's assets, other than intellectual property, with respect to which the Company and ImaTx granted

a negative pledge. The 2014 Secured Loan Agreement contained negative covenants restricting its activities, including limitations on dispositions, mergers or acquisitions, incurring indebtedness or liens, paying dividends or making investments and certain other business transactions. There were no financial covenants associated with the 2014 Secured Loan Agreement. Obligations under the 2014 Secured Loan Agreement were subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the business, operations or financial or other condition.

No advances were outstanding from the Revolving Line at any time. Administrative and legal costs in connection with the 2014 Secured Loan Agreement were deemed immaterial and expensed as incurred.

In connection with the SVB/Oxford Term Loan A, the Company issued warrants to purchase an aggregate of 33,481 shares of the Company's common stock at a price of $8.96 per share, which was the fair value of the Company's common stock. Based on the Company's assessment of the warrants relative to ASC 480, Distinguishing Liabilities from Equity, the warrants were classified as equity and the Company recorded $134,000 fair value of the warrants as a discount to the term loan recorded to additional paid-in capital. In November 2015, these warrants were exercised.

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

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

$15 million term loan—WTI Term Loan II

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

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

$1.4 million term loan—Massachusetts Development Finance Agency

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

At the time the Company entered into the MDFA facility, the Company borrowed the first tranche of $0.6 million, with the remaining funds to be borrowed over the following 18 months. To date, the Company has borrowed a total of $1.4 million of the available commitments under the facility, of which $0.5 million in loans were outstanding as of December 31, 2015 and $0.8 million were outstanding as of December 31, 2014. Loans under the MDFA facility bear

a fixed interest rate of 6.5% per annum. Interest is payable monthly in arrears. Beginning on January 1, 2013, the Company began making payments of principal and interest in 66 equal monthly installments.

In connection with the MDFA facility, the Company issued warrants to MDFA to purchase 16,000 shares of Series D preferred stock. Based on the Company's assessment of the warrants relative to ASC 480, Distinguishing

Liabilities from Equity, the warrants are classified as equity and the Company recorded fair value of $46,000 as a discount to the term loan and was amortized to interest expense over the 84-month life of the term loan.

Note L—Related Party Transactions

Vertegen

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

In connection with entering into the license agreement with Vertegen, the Company paid Vertegen an initial license fee of $10,000 and issued Vertegen a warrant to purchase 100,000 shares of its common stock at an exercise price of $1.10 per share, which has expired unexercised. Pursuant to the Vertegen Agreement, the Company is required to pay Vertegen a 6% royalty on net sales of products covered by the patents licensed to us by Vertegen, the subject matter of which is directed primarily to spinal implants, and any proceeds from the Company enforcing the patent rights licensed to the Company by Vertegen. Such 6% royalty rate will be reduced to 3% in the United States during the five-year period following the expiration of the last-to-expire applicable patent in the United States and in the rest of the world during the five-year period following the expiration of the last-to-expire patent anywhere in the world. The Company has not sold any products subject to this agreement and has paid no royalties under this agreement. The Company has paid approximately $140,000 in expenses as of December 31, 2015 in connection with the filing and prosecution of the patent applications licensed to the Company by Vertegen.

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

Asia strategy

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

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

Based on the restriction on the use of the proceeds received in connection with the letter agreement, the proceeds were classified as restricted cash and an investment activity. Upon the closing of the Company's IPO in July 2015, pursuant to the conditions of the letter agreement in connection with the Asia strategy, $3.5 million of the proceeds received in

connection with the letter agreement were reclassified from restricted cash to cash and cash equivalents. As of December 31, 2015, $0 million of the proceeds and as of December 31, 2014, $3.6 million of the proceeds were included in restricted cash.

Revenue share agreement

As described in Note J, the Company is a party to certain agreements with advisors to participate as a member of the Company's scientific advisory board. In September 2011, the Company entered into an amended and restated revenue share agreement with Philipp Lang, M.D., the Company's Chief Executive Officer, which amended and restated a similar agreement entered into in 2008 when Dr. Lang stepped down as chair of the Company's scientific advisory board and became the Company's Chief Executive Officer. This agreement provides that the Company will pay Dr. Lang a specified percentage of our net revenues, ranging from 0.875% to 1.33%, with respect to all of our current and planned products, including the Company's iUni, iDuo, iTotal CR, iTotal PS and iTotal Hip products, as well as certain other knee, hip and shoulder replacement products and related instrumentation the Company may develop in the future. The specific percentage is determined by reference to product classifications set forth in the agreement and is tiered based on the level of net revenues collected by the Company on such product sales. The Company's payment obligations expire on a product-by-product basis on the last to expire of the Company's patents on which Dr. Lang is a named inventor that claim the applicable product. These payment obligations survive any termination of Dr. Lang's employment with the Company. The Company incurred revenue share expense paid to Dr. Lang of $0.8 million, $0.6 million and $0.4 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Note M—Stockholders' Equity

Common stock

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

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

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

Summary of common stock activity was as follows:

	Shares
Outstanding December 31, 2013	4,161,178
Issuance of common stock - option & warrant exercises	124,986
Outstanding December 31, 2014	4,286,164
Issuance of common stock - option & warrant exercises	395,192
Issuance of restricted common stock	174,530
Issuance of common stock - IPO	10,350,000
Issuance of common stock - preferred stock conversion to common stock	25,904,241
Outstanding December 31, 2015	41,110,127

Preferred stock

Prior to the filing of the Company's Restated Certificate of Incorporation upon closing if its IPO, the Company was authorized to issue 53,496,241 shares of $0.00001 par value preferred stock. The Company's Restated Certificate of Incorporation authorizes the Company to issue 5,000,000 shares of preferred stock, $0.00001 par value, all of which is undesignated.

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

Series	Shares Authorized	Shares Issued and Outstanding	Liquidation Value
Series A convertible preferred	3,410,278	3,410,278	$3,410
Series B convertible preferred	4,469,349	4,469,349	12,023
Series C convertible preferred	5,191,754	4,906,040	17,171
Series D convertible preferred	14,612,360	13,307,287	79,844