ConforMIS Inc
Form 10-K
March 09, 2018

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, 2017

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number: 001-37474

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

Delaware	56-2463152
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
600 Technology Park Drive Billerica, MA	01821
(Address of principal executive offices)	(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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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. o

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

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

The aggregate market value of Common Stock held by non-affiliates of the registrant computed by reference to the price of the registrant's Common Stock as of the last business day of the registrant's most recently completed second fiscal quarter (based on the last reported sale price on The Nasdaq Global Select Market as of such date) was $94,870,205. As of February 28, 2018 there were 60,861,852 shares of the registrant's Common Stock, $.00001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2017. Portions of such definitive proxy statement are incorporated by reference into 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 iUni, iDuo, iTotal CR, iTotal PS and ConforMIS Hip System, which we previously referred to as our iTotal Hip system;
- our expectations regarding our sales, expenses, gross margin 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 anticipated timing of our product launches;
- 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;
- 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 anticipated adequacy of our capital resources to meet the needs of our business or our ability to raise any additional capital; 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 $17.5 billion annually and growing, and we believe our iFit technology platform is applicable to all major joints in this market. We offer 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 50,000 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 off-the-shelf implants. In March 2016, we initiated the broad commercial launch of the iTotal PS, our posterior-stabilized total knee replacement implant which addresses the largest segment of the knee replacement market.

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 that we may extend 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 off-the-shelf 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.

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 patients, surgeons and hospitals 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. A study of 63 knee replacement surgeries, published in 2017 in the peer-reviewed Journal of Knee Surgery, indicates that 84% of patients achieved perfect neutral coronal mechanical alignment after surgery, and that 100% of patients were within the desired alignment range after surgery. Similarly, a prior retrospective study of 200 knee replacement surgeries published in 2014 in the peer-reviewed Journal of Arthroplasty, or the 2014 JOA Study, indicated 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 the 2014 JOA Study was conducted, one of the authors of this study was a paid consultant to us.

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- 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;
- reducing the costs associated with managing and sterilizing large numbers of reusable instruments;
- 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 28, 2018, we own or exclusively in-license a total of approximately 420 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 148 issued United States patents, 67 patents issued in countries outside the United States, and 205 patent applications worldwide. See Note J - "Legal Proceedings" in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K for information regarding our patent litigation.

All of our knee replacement products have been cleared by the U. S. Food and Drug 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, 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.

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.

Joint replacement market

According to the Orthopaedic Industry Annual Report for the 2016 calendar year, which was published in May 2017 by Orthoworld Inc., or the 2016 Orthoworld Report, worldwide sales of joint replacement products, including replacements for knees, hips, shoulders, elbows, wrists, ankles and digits outside of trauma, exceeded $17.5 billion in 2016 and are expected to grow to approximately $21 billion by the end of 2021. The 2016 Orthoworld Report estimated that worldwide sales of knee replacement products totaled approximately $8.5 billion and the United States represented approximately 49% of total estimated worldwide sales of such products. In 2016, according to the 2016 Orthoworld Report, worldwide sales of hip replacement products totaled approximately $6.9 billion. According to the 2016 Orthoworld Report, 2016 estimated sales of hip replacement products in the United States represented approximately 40% of total estimated worldwide sales of such products. According to the 2013 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 2016 Orthoworld Report, the worldwide extremities joint replacement market was estimated at $1.9 billion in 2016.

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. 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 may extend 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

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 patients, surgeons and hospitals 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.

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.

Greater patient satisfaction. We believe that, as a result of our customized implants fitting and functioning better, patients have greater overall satisfaction with the results of their knee replacement.

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.

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. At the time of the study, two of the authors of this study were our employees, and two of the authors of this study were 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 a peer reviewed study of 169 implants published in Reconstructive Review in 2016 indicates that our iTotal CR showed statistically significant less bone loss resection ($p \leq 0.05$) when compared to off-the-shelf implants. At the time of the study, two of the authors of this study were our employees, and one of the authors of this study was a paid consultant to us.

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, published in the peer-reviewed journal Arthroplasty Today in 2017, or the 2017 AT Study, indicates that patients who received an iTotal CR had significantly lower transfusion rates ($p=0.005$) and adverse event rates at discharge ($p=0.003$) and at 90 days post-discharge ($p=0.023$) than patients who received an off-the-shelf total knee replacement implant. We provided financial support for this study. At the time of this study, one of the authors of this study 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 2015 ICJR World Arthroplasty Congress 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, 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 2017 AT 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%). Our summary of a study presented at the ICJR Pan Pacific Orthopaedic Congress in 2016, of 62 patients with either our iTotal CR or an off-the-shelf implant in a “Fast Track” protocol, also indicates that a significantly higher (p≤0.05) proportion of iTotal CR patients (66%) were discharged in less than 1 day when compared to off-the-shelf patients (30%).

- Economic Savings. We believe that our technology offers the potential of significant economic savings to hospitals and payors. For example, the 2017 AT Study compared adverse events rates and cost of care for total knee arthroplasty (TKA) patients treated with either customized individually made (CIM) implants or standard off-the-shelf (OTS) implants. In that study, the total average real hospital costs between the customized implant and OTS groups were nearly identical (customized implant $16,192 vs OTS $16,240), suggesting that patients with customized implants received improved hospital outcomes at no additional cost to the hospital. However, risk-adjusted per patient total cost of care showed a net savings of $913.87 per patient for the customized implant group for bundle of care, including the preoperative computed tomography scan, TKA hospitalization, and discharge disposition. Follow-up care costs demonstrated a savings of $1,313 per patient.

- 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 reusable instruments are not properly prepared prior to surgery, they are a potential source of costly infections. The lower number of reusable instruments used with our knee implants reduces the possibility of contaminated instruments. Our summary of the results of the 2017 AT 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 this published research, sponsored by us, also indicates that use of our iTotal CR is associated with lower adverse event rates during the 90-day period following surgery (p=0.023). 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:

- 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.

- Leverage 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.

- 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 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 2017, we received clearance from the FDA for the ConforMIS Hip System, our first customized hip replacement implant, which we plan to launch on a limited basis in the second half of 2018. Additionally, we are currently developing the next generation of our iUni partial knee replacement system, which we expect to launch on a limited basis in the first half of 2019, and we are developing the next generation of our iTotal CR and iTotal PS systems. We expect to launch the next generation of the iTotal CR in the second half of 2019, including the launch of instrumentation that will be used in our next generation iTotal PS system. 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 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:
  - expansion of gross margin through various initiatives, including the ongoing vertical integration of some of our manufacturing processes;
  - shorter product design and development time frames; and
  - continuous improvement of our products without making obsolete a large inventory of implants and instruments, in contrast to manufacturers of off-the-shelf implants;

- Enhance our patent portfolio and continue to exploit our patent position. As of February 28, 2018, we own or exclusively in-license a total of approximately 420 issued patents and pending patent applications that cover customized implants and PSI for all major joints and other elements of our iFit technology platform. See Note J - "Commitments and Contingencies" in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K for information regarding our patent litigation.

Our products

Knee replacement products

We offer a broad line of primary knee replacement implants, both partial and total, that we customize to fit the individual 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. 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. 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

ConforMIS Hip System

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. Also, 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. On June 14, 2017, we received FDA 510(k) clearance for our ConforMIS Hip System product, and we expect to launch the system on a limited basis in the second half of 2018. We believe the introduction of the ConforMIS Hip System will provide synergies with our existing line of customized knee implants because most surgeons who perform knee replacements also perform hip replacements. Thus, we believe that the ConforMIS Hip System complements our existing product line, customer base, sales force and distribution channels.

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 5 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.

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 28, 2018, there were 17 peer-reviewed journal articles and 45 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.

Sales and marketing

We market and sell our products in the United States, Germany, the United Kingdom, Austria, Ireland, Switzerland, Singapore, Hong Kong, Malaysia and Monaco. 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 expect to expand the size of our sales and marketing capabilities by entering into additional direct sales, independent sales and distributor representative 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.

As part of our targeted regional commercial strategy, we identify markets in the United States based on knee replacement procedure volume, surgeon density, prevailing average selling price for a knee replacement, and other factors. 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.

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 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 31 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, 2017, 2016 and 2015, company-sponsored research and development expense was $17.1 million, $16.6 million and $17.0 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 Wilmington, Massachusetts and Wallingford, Connecticut.

We produce our CAD designs in-house and in India and use them to direct all of our product manufacturing efforts. As part of our manufacturing cost reduction efforts, in 2017, we continued expanding our CAD labor force in India.

We manufacture all of our patient-specific instruments, or iJigs, tibial trays used in our total knee implants, and, starting in May 2017, polyethylene tibia tray inserts for our iTotal CR product and, starting in December 2017, our iTotal PS product, at our facility in Wilmington, Massachusetts. In August 2017, we completed the purchase of certain assets and assumed certain liabilities of Broad Peak Manufacturing, LLC or BPM. Prior to the acquisition, BPM provided substantially all of the polishing services for the Company’s femoral implant component. Subsequent to the BPM acquisition, we also began to passivate our femoral implant components in our facilities in Wallingford, Connecticut. We outsource the production of the femoral and other implant components to third-party suppliers. 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 most of 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:

- continue to 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;
- continue to explore 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;
- continue expanding our CAD labor force in India; 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 patient-specific 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 patient-specific instruments. As a result, 3D printing plays a key 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 continue to evaluate integrating DMLS into our manufacturing process.

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 meet specified requirements. Members of our quality department also inspect our devices at various stages during the manufacturing cycle to ensure quality to specifications. Our quality department periodically audits our suppliers to ensure compliance to appropriate ISO standards, FDA regulations and to our specifications, policies and procedures for our devices.

We and our suppliers are subject to extensive regulation by the FDA under its Quality System Regulation, or QSR. The QSR requires manufacturers to 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 and/or verified the processes used in the manufacturing and testing of our devices. Our Wilmington and Wallingford 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 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 28, 2018, we owned or exclusively in-licensed 215 issued patents around the world, including 148 patents issued in the United States and 67 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.

As of February 28, 2018, we owned or exclusively in-licensed 205 patent applications, including 59 patent applications pending in the United States and 146 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 2036. 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

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, which we amended on June 13, 2016, or the Smith & Nephew Lawsuit. The Smith & Nephew Lawsuit alleges that Smith & Nephew’s Visionaire® patient-specific instrumentation as well as the implants systems used in conjunction with the Visionaire instrumentation

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infringe nine of our patents, and it requests, among other relief, monetary damages for willful infringement, enhanced damages and a permanent injunction.

On May 27, 2016, Smith & Nephew filed its Answer and Counterclaims in response to our lawsuit, which it subsequently amended on July 22, 2016. Smith & Nephew denied that its Visionaire® patient-specific instrumentation as well as the implants systems used in conjunction with the Visionaire instrumentation infringe the patents asserted by us in the lawsuit. It also alleged two affirmative defenses: that the patents that we asserted are invalid and that we are barred from relief under the doctrine of laches. In addition, Smith & Nephew asserted a series of counterclaims, including counterclaims seeking declaratory judgments that Smith & Nephew's accused products do not infringe our patents and our patents are invalid. Smith & Nephew also alleged that we infringe ten patents owned or exclusively licensed by Smith & Nephew: two patents that Smith & Nephew alleges are infringed by our iUni and iDuo products; three patents that Smith & Nephew alleges are infringed by our iTotal products; and five patents that Smith & Nephew licenses from Kinamed, Inc. of Camarillo, California and that it alleges are infringed by our iUni, iDuo and iTotal products. Due to Smith & Nephew's licensing arrangement with Kinamed, Kinamed was named as a party to the lawsuit. Smith & Nephew and Kinamed requested, among other relief, monetary damages for willful infringement, enhanced damages and a permanent injunction. On March 9, 2017, the Court entered a stipulation of dismissal by the parties that dismissed from the lawsuit eight patents asserted by Smith & Nephew, including the patents involving Kinamed, and two patents asserted by us.

Between September 21, 2016 and March 1, 2017, Smith & Nephew filed sixteen petitions with the United States Patent & Trademark Office, or USPTO, requesting Inter Partes Review, or IPR, of the nine patents that we asserted against Smith & Nephew in the lawsuit. In its petitions, Smith & Nephew alleged that our patents are obvious in light of certain prior art. As of October 31, 2017, the USPTO decided to institute IPR proceedings with respect to seven of the petitions; decided to deny the requests for IPR with respect to seven of the petitions; and, with respect to the remaining two petitions, decided to institute IPR proceedings for some of the subject patent claims and to deny the requests for the remaining subject patent claims. In total, the USPTO instituted IPR proceedings for some or all of the subject patent claims in six of the patents in the Smith & Nephew lawsuit (five patents that are currently asserted, and one of the patents that was voluntarily dismissed from the lawsuit), and denied the petitions for all subject claims in three of the patents (two patents that are currently asserted and one of the patents that was voluntarily dismissed from the lawsuit). Smith & Nephew filed requests for rehearing in three of the petitions that were either partially or completely denied and filed requests for reexamination of two of the patents for which no IPR was instituted. The requests for rehearing were denied.

On January 27, 2017, Smith & Nephew filed a motion seeking a stay of the Smith & Nephew Lawsuit until any requested Inter Partes Reviews are resolved, and we filed an opposition to that motion. On April 27, 2017, the Court stayed certain aspects of the proceedings and indicated that it will make a final decision on the motion to stay after the USPTO has decided more of the petitions for Inter Partes Review. We are presently unable to predict the outcome of the motion to stay the proceedings, the instituted IPRs, the reexaminations, or the Smith & Nephew Lawsuit. An adverse outcome of some or all of the IPR proceedings, the reexamination or the Smith & Nephew Lawsuit could have a material adverse effect on our business, financial condition or results of operations.

Licenses to others

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 28, 2018, we have filed 152 trademark registrations in the United States and in other major markets worldwide, including the following marks: ConforMIS, iFit, iTotal, iDuo, and iUni. We have 18 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, Stryker Corporation, or Stryker, DePuy Synthes, Inc., or DePuy, a Johnson & Johnson company and Smith & Nephew, Inc., or Smith & Nephew. 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, with a premium of five percent on average.

Regulatory requirements

Our medical device products are subject to extensive regulation by government agencies and other authorities in the United States and in other countries and jurisdictions, including the EU. These governmental authorities regulate the introduction of medical devices into their respective geographies within their jurisdiction. The regulations cover the entire life cycle of the product, including the research, development, testing, manufacture, quality control, packaging, storage, labeling, advertising and promotion of the devices. In addition, post-approval monitoring and reporting, as well as import and export of medical devices, are subject to regulatory requirements. The processes for obtaining regulatory approvals or clearances in the United States and in foreign countries and

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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 Code of Federal Regulation, 21 CFR Parts 800-1299, Food and Drugs, 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 cleared 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 and the novelty of the medical device. 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 the 510(k) premarket notification process to obtain regulatory clearance from the FDA for the marketing, sale and distribution 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. On June 14, 2017, we received FDA 510(k) clearance of our ConforMIS Hip System.

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

Review and approval of medical devices in the EU

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.

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 May 8, 2021 for our iTotal CR product, December 2, 2022 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.

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. These new regulations, adopted April 5, 2017, and expected to be fully implemented within 3 years, 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, which could harm our business."

Third-party reimbursement

In the United States and most other major joint implant markets, many 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.

In January 2017, the rate of reimbursement for surgical procedures using our products in Germany was changed. Previously, all procedures in which our products were used were reimbursed under the same reimbursement code, or "Sonderprothesen", OPS code 5.822.91. Beginning January 1, 2017, the reimbursement for surgical procedures using our iTotal CR and iTotal PS products increased by approximately 3.7%, while the reimbursement for surgical procedures using our iUni products decreased by approximately 36.3%, and the reimbursement for surgical procedures using our iDuo products decreased by approximately 27.0%. We believe that the change in the rate of reimbursement for surgical procedures using our iTotal CR and iTotal PS products has not materially impacted sales in Germany. However, the decrease in the rate of reimbursement for surgical procedures using our iUni and iDuo products has adversely impacted our sales in Germany.

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 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. In particular, the General Data Protection Regulation, or GDPR, is a regulation in the European Union, or EU, that, among other things, unifies data protection regulation within the EU and governs the export of certain personal data and health information of citizens of the EU. The regulations will be enforced beginning May 25, 2018, following a two-year transition period.

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 the United Kingdom predominately and several 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 and health technology assessment schemes, government-mandated collection periods, patient privacy laws and regulations, and other data privacy laws and regulations.

Employees

As of February 28, 2018, we had 350 employees, including 348 full-time employees, 68 of whom were engaged in sales and marketing, 31 in research and development, 170 in manufacturing and service, 37 in regulatory, clinical affairs and quality activities and 44 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 600 Technology Park Drive, Billerica, MA 01821, 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 $54 million for the year ended December 31, 2017, $58 million for the year ended December 31, 2016 and $57 million for the year ended December 31, 2015. As of December 31, 2017, we had an accumulated deficit of $437 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 likely will 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 new versions of our existing products and 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 may 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 in the future will be revenue generated from the sales of our products, potential future capital raises through the issuance of equity or other securities, revenue that we may generate in connection with licensing our intellectual property, and potentially borrowings under our 2017 Secured Loan Agreement, described in Note K to the Consolidated Financial Statements included in this Annual Report on Form 10-K. 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.

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, we may subsequently 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 be required to scale back our operations.

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We expect to engage in additional equity or debt financings to secure additional funds within the next two years, and we may need to engage in additional equity or debt financings to secure additional funds after that. 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 equity or debt securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders or involve negative covenants that restrict our ability to take specific actions, such as incurring additional debt or making capital expenditures.

Risks related to our business, industry and competitive position

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

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

In addition, as part of our commercial strategy we work to significantly increase our sales in targeted markets by focusing on high-volume, influential surgeons who use our products. As a result, orders from a relatively small number of surgeons provide a significant portion of our total revenue. The loss of, or significant curtailment of orders by, a limited number of our high-volume doctors, including curtailments due to reduced reimbursement rates, medical policy coverage denials, adoption of our competitors’ products or the timing of orders by these doctors, may adversely affect our results of operations and financial condition.

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

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 have expanded our product offerings to include the ConforMIS Hip System, for which we received FDA approval on June 14, 2017. However, we may not be able to successfully commercialize the ConforMIS Hip System on a timely basis, or at all. Any factors that delay the commercial launch of, including the process for obtaining additional regulatory clearance as may be needed for full launch of the ConforMIS Hip System, additional products, or result in sales of 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 additional products, there can be no assurance that these additional products will be accepted in the market or commercially successful or profitable.

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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 may enjoy several competitive advantages over us, including:

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

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 and increase our gross margin, we will need to significantly increase sales of our existing products, expand our manufacturing capabilities, and successfully develop and commercially launch future products at a scale that we have not yet achieved. In order to increase our gross margin 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;

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- 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.

We may not be successful in achieving these objectives, and our gross margin may not increase, or could even decrease. We may not be successful in executing on our business model, in increasing our gross margin 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;
- 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
- 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 were 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.

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

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

To date, we have collected only limited clinical data regarding our iTotal PS knee replacement product, and no clinical data on our ConforMIS Hip System 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 or may not be considered sufficient by patients, surgeons, hospitals, or payors. We are aware of three such clinical studies. The first was published in the Journal of Arthroplasty in 2016, 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 CR 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 the patient's two year follow-up), Satisfaction and KSS pain scores at two years post-surgery and manipulation under anesthesia, or MUA, a procedure used post-operatively to adjust a knee replacement implant to improve its function. The second such study was published in Kansas Journal of Medicine in 2016 and investigated MUA rates in 21 patients with the iTotal CR and 57 patients with an off-the-shelf PS implant performed by a single surgeon. The measures on which our iTotal CR product performed less well than the off-the-shelf products were range of motion at six weeks and MUA rates. However, in a multi-center study of our iTotal CR product involving 360 patients for which we provided financial support, the 3.11% rate of MUA for our iTotal CR product was substantially lower than the 28.6% rate of MUA shown in these single surgeon studies. Additionally, the patients who had completed their one year follow-up in the multicenter study reported a 92% satisfaction rate. 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%. The third such study was presented as an abstract at the 2017 American Association of Hip and Knee Surgeons meeting, conducted by a single surgeon involving 115 of our iUni implants. Patients in this study experienced a higher than typical revision rate than is typically noted in literature when reviewing comparable implants. However, in both a multi-center study and in a single-center study of our iUni products, for which we provided financial support, involving 120 patients and 25 patients respectively, revision rates are consistent with, or lower than, reported rates for other off-the-shelf unicompartmental implants.

In addition, 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 or hip products. 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 hip products. 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 and third-party payers may decide to restrict medical policy coverage and payment for procedures involving our technology. 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. We believe that offering a broad line of joint replacement products is important to convincing surgeons to use our products generally. If market acceptance of either our iTotal PS or our ConforMIS Hip System 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 research and development efforts may result in products or technologies for which market demand is lower than anticipated or for which we are otherwise unable to adequately commercialize and, as a result, abandon, defer or modify such efforts. 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 to successfully 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 medical policy coverage and reimbursement of procedures that utilize our products.

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

In the United States, surgeons and hospitals and other medical facilities who purchase medical devices such as our products generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to pay for all or a portion of the costs and fees associated with the joint replacement surgery and the products utilized in the procedure, including the cost of our products. Our customers' access to adequate coverage and reimbursement for the procedures performed using our products by government and third-party payors is central to the acceptance of our current and future products. Payors may view new products or products that have only recently been launched or with limited clinical data available, including the iUni, iDuo, iTotal CR, iTotal PS and ConforMIS Hip System, as investigational, unproven or experimental, or not medically necessary, and on that basis may deny coverage of procedures involving use of our products. For example, we are aware of certain private insurers that at this time consider the use of custom implants or patient-specific instrumentation for knee replacement surgery as investigational, unproven or experimental or not medically necessary. In addition, the American Academy of Orthopedic Surgeons currently has published clinical guidelines that do not support the widespread use of patient-specific instrumentation in total knee arthroplasty generally, at least until additional data regarding any purported advantages can be considered. We may be unable to sell our products on a profitable basis if government and third-party payors deny coverage for such procedures or set reimbursement rates at unfavorable levels for procedures involving use of our products.

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

An initial 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, and some third-party payors may have policies against reimbursement of such scans when they have not been deemed medically necessary. 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 and also not always reimbursed by third-party payors when related to joint replacement procedures. 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 events, our costs of sales could increase and our revenue could decrease, in each case adversely affecting our financials, including, among other things, our gross margin.

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 calculate a set payment per beneficiary or member of the ACO based on the specific ACOs' historical aggregate payments for care provided to the respective beneficiaries, or in the instance of the Comprehensive Care for Joint Replacement initiative a regional per procedure payment, known as a "bundle", would be calculated. 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.

U.S. President Donald Trump and other U.S. lawmakers have made statements about potentially repealing and/or replacing the PPACA and other associated laws, although specific legislation for such a repeal or replacement has not yet been introduced. To the extent that future changes affect how our products are paid for and reimbursed by government and private payers, or otherwise affect our business, our business could be adversely impacted.

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 in the past we have attained reimbursement rates at higher price points than some competitive products, has changed negatively for certain of our products and could further change negatively in Germany and other jurisdictions.

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

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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 and Germany. 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 revenue 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, the United Kingdom, Switzerland, Hong Kong and Singapore. Revenue generated from the sales of our products by independent sales representatives represented approximately 78% of our total revenue from sales of our products in the United States for the year ended December 31, 2017, approximately 71% of our total revenue from sales of our products in the United States for the year ended December 31, 2016 and approximately 61% of our total revenue from sales of our products in the United States for the year ended December 31, 2015. 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, 2017, 2016 and 2015. Revenue generated from the sales of our products to distributors represented approximately 14%, 5% and 4% of our total revenue from sales of our products outside the United States for the years ended December 31, 2017, 2016, and 2015. We did not generate any revenue from sales of our products to distributors in the United States in the years ended December 31, 2017, 2016 and 2015. We have entered into agreements with these independent sales representatives and distributors; we have a limited ability, however, to influence the efforts of these independent sales representatives and distributors. Relying on independent sales representatives and distributors for our sales and marketing could harm our business for various reasons, including:

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

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

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Global economic conditions 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. Declines in employment rates or consumer confidence both in the United States and abroad could result in reduced numbers of insured patients and the deferral of some elective joint replacement procedures. Similarly, uncertainty about the stability of global financial markets could adversely affect our operations. Challenges and pressures in the global economy could 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 could have a 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 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 any disruption in financial markets and adverse economic conditions, or the effects these disruptions and conditions would have on us.

The exit of the United Kingdom from membership in the European Union could adversely affect our financial results and our operations in the United Kingdom and the European Union.

The passage of the Referendum of the United Kingdom’s, or the U.K., Membership of the European Union (E.U.), or Brexit, providing for the exit of the United Kingdom from the European Union, could adversely affect our sales in the U.K., as well as our existing and future customers and employees in E.U. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which E.U. laws to replace or replicate. The measures could potentially disrupt the markets we serve and the tax jurisdictions in which we operate and adversely change tax benefits or liabilities in these or other jurisdictions, and may cause us to lose customers and employees. Furthermore, we translate sales and other results denominated in foreign currency into U.S. dollars for our financial statements. Volatility in stock or currency markets, as well as the strengthening of the U.S. dollar relative to other currencies each could adversely affect our financial results.

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.

In January 2017, we entered into a senior secured $50 million loan and security agreement (the "2017 Secured Loan Agreement") with Oxford Finance, LLC ("Oxford"), consisting of three term loans issued by Oxford, (the "Oxford Term Loans"), with $15 million issued for each of the first two term loans and $20 million issued for the third term loan, in each case, subject to the satisfaction of certain revenue milestones and customary drawdown

conditions. Through the Secured Loan Agreement with Oxford, the Company accessed $15 million of borrowings on January 6, 2017 and a second $15 million of borrowings on June 30, 2017, with an additional $20 million potentially available to borrow through June 2018, at our option, but subject to the satisfaction of certain revenue milestones and customary drawdown conditions, which we do not expect will be satisfied by the end of June 2018. For further information regarding this facility, see “Note K—Debt and Notes Payable—2017 Secured Loan Agreement” in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. The credit facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide Oxford, as collateral agent with the right to exercise remedies against us and the collateral securing the credit facility, including foreclosure against assets securing the credit facilities, including the Company’s cash. These events of default include, among other things, the Company’s failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, the Company’s failure to meet defined measures of financial performance, the Company’s insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $500,000, one or more judgments against us in an amount greater than $500,000, a material adverse change with respect to any governmental approval and any delisting event. As of December 31, 2017, we were not in breach of covenants under the credit facility.

Our 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.

Additionally, with respect to our current indebtedness and any future debt that we may secure, our failure to perform financially according to the terms of the loan agreement or otherwise perform or satisfy the covenants of the loan agreement could materially adversely affect us, for example, by causing us to pay increased interest, causing us to have to repay some or all of the principal of the loan on an accelerated basis, providing the lender with the ability to foreclose the loan, causing the lender to have recourse against some or all of our assets used as collateral in the loan, including, without limitation, our cash, our intellectual property, any other of our assets, and triggering other potentially adverse consequences under the terms of any loan agreement.

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

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

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

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

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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 manufacture our products at our facilities in Wilmington, Massachusetts, and Wallingford, Connecticut. Certain manufacturing processes in our facilities may require process and/or equipment validation and are subject to FDA inspections, as well as inspections and audits by international regulatory agencies, including Notified Bodies for the European Union. We have completed all appropriate process and/or equipment validations of our manufacturing processes for implant components and instrumentation manufactured at our Wilmington and Wallingford facilities. 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.

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 may 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. We have no commercial manufacturing experience with respect to the ConforMIS Hip System and any future products that we may develop.

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, due to our inability to meet demand with in-house production or with outside suppliers, 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 manufacturing equipment;
- 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.

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 purchase raw materials, including polymer powders, tibial tray blanks, and polyethylene blocks 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. 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. Because we rely on these few suppliers and generally maintain a forward inventory of these materials sufficient only for approximately three 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 certain raw materials. These sole source suppliers may be unwilling or unable to supply 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.

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

We generally purchase our outsourced implant components through purchase orders and do not have long-term contractual arrangements with any of our key suppliers. As a result, our suppliers have no obligation to manufacture for us or sell to us any given quantity of implant components. Without such contractual commitments, we could face difficulties in obtaining acceptance for our purchase orders, which could impair our ability to purchase adequate quantities of our implant components. If we are unable to obtain sufficient quantities of high-quality,

individually-made components to meet demand on a timely basis, we could lose customers, our reputation may be harmed and our business would suffer. In addition, we currently depend on sole source suppliers for the supply of

the reusable instrument trays and related logistics associated with our implant products. These sole source suppliers may be unwilling or unable to supply the trays and logistics services to us reliably, continuously and at the levels we anticipate or are required by the market.

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

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

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

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

Moreover, our suppliers are dependent on commercial freight carriers to deliver implant components to our facilities, and we are dependent on commercial freight carriers to deliver our finished products to hospitals and surgeons. If the operations of these carriers are disrupted for any reason, we may be unable to deliver our products to our customers on a timely basis. If we cannot deliver our products in an efficient and timely manner, our customers may reduce their orders from us and our revenue 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 revenue, 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 revenue and operating results.

A cyber security incident could result in a loss of confidential data, give rise to remediation and other expenses, expose us to liability under HIPAA, consumer protection laws, or other common law theories, subject us to litigation and federal and state governmental inquiries, damage our reputation, and otherwise be disruptive to our business.

We collect and store sensitive information, including intellectual property and personally identifiable information, on our networks. The secure maintenance of this information is critical to our business operations. We have implemented multiple layers of security measures to protect this confidential data through technology, processes, and our people; we utilize current security technologies; and our defenses are monitored and routinely reviewed by internal and external parties. Despite these efforts, threats from malicious persons and groups, new vulnerabilities, and advanced new attacks against information systems create risk of cyber security incidents. There can be no assurance that we will not be subject to cyber security incidents that bypass our security measures, result in loss of personal health information or other data subject to privacy laws or disrupt our information systems or business. As a result, cyber security and the continued development and enhancement of our controls, processes and practices designed to protect our information systems from attack, damage or unauthorized access remain a priority for us. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any cyber security vulnerabilities. The occurrence of any of these events could result in interruptions, delays, the loss, access, misappropriation, disclosure or corruption of data, liability under privacy, security and consumer protection laws or litigation under these or other laws, including common law theories, and subject us to federal and state governmental inquiries, any of which could have a material adverse effect on our financial position and results of operations and harm our business reputation.

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, Hong Kong, Malaysia and Monaco. We expect that our international activities will increase over the foreseeable future as we continue to pursue opportunities in additional international markets. During each of the years ended December 31, 2017, 2016 and 2015 approximately 16%, 21% and 25% of our revenue was attributable to our international customers, respectively, and as of December 31, 2017, approximately 4% of our employees were located outside the United States. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subjects us to extensive U.S., Canadian, EU and other foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Therefore, we are subject to risks associated with having international operations. These international operations will require significant management attention and financial resources.

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

- requirements or preferences for domestic products or solutions, which could reduce demand for our products;
- differing existing or future regulatory and certification requirements;
- technology assessment requirements that we are not able to satisfactorily meet with our current published clinical and health economic outcomes studies;
- 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 of 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;

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- 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;
- 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 margin 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 growth in the number of our employees and the scope of our operations, particularly in the areas of manufacturing and sales, 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. We may have difficulties effectively managing the expansion of our operations or recruiting and training 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 revenue 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 principal members of our management, scientific and development teams, including Mark Augusti, our President and Chief Executive Officer, and Daniel Steines, our Chief Technology Officer. 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

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

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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 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 manufacturing 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. 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 revenue, 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 any of our license agreements, our counterparties may have the right to seek relief or 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.

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

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

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Further, as the number of participants in the joint replacement industry grows, the possibility of intellectual property infringement claims against us increases. 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.

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. 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.

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 replacement procedures. Knee replacement surgery, as well as other joint replacement surgery, involves significant risk of serious complications, including bleeding, infection, instability, dislocation, 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. 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

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- 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; and
- 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 or an institutional review board 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;
- patients may not enroll in clinical trials, or patient follow-up may not occur, at the rate we expect;
- patients may not comply with trial protocols;
- third-party organizations may not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical trials or manufacturing facilities may, among other things, require us to undertake corrective action or suspend, terminate or invalidate our clinical trials;
- changes in governmental regulations or administrative actions; and
- the interim or final results of the clinical trials may be inconclusive or unfavorable as to safety or effectiveness.

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

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

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

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of products we are developing or impact our ability to modify any of our products for which we receive regulatory clearance or approval in the future on a timely basis. Any change in the laws or regulations that govern the clearance and approval

processes relating to the products we are developing could make it more difficult and costly to obtain clearance or approval for such products, or to produce, market and distribute products for which we receive regulatory approval or clearance in the future.

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

As part of the conformity assessment process, depending on the type of device, an entity authorized to conduct the conformity assessment, which is referred to as a Notified Body, will review the manufacturer's clinical evaluation process, assess the clinical evaluation data of a representative sample of the device's subcategory or generic group, or assess all the clinical evaluation data, verify the manufacturer's assessment of that data and assess the validity of the clinical evaluation report and the conclusions drawn by the manufacturer. We conduct clinical studies to obtain clinical data as part of the clinical evaluation process. The conduct of clinical studies to obtain clinical data that is currently required or that might be required in the future 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 current CE Certificates of Conformity are valid through May 8, 2021 for our iTotal CR product, December 2, 2022 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. Additionally, the planned exit of the United Kingdom from membership of the European Union, or Brexit, could affect the requirements for selling medical devices in the United Kingdom, which would adversely affect our business if we are unable to meet such requirements at all or in a timely manner.

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 has adopted newly revised regulations that may impact and 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 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. 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;
- 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;
- repair, replacement, refunds, recalls or detention of our products;
- fines, restitution or disgorgement of profits or revenue;
- 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

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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. 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. We cannot provide assurances regarding the outcome of any such audits.

The British Standards Institute, or BSI, an independent global notified body, conducts periodic 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.

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 voluntary product recalls 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.

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

stock recovery involving our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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

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

In particular, our voluntary recall announced in August 2015 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 and other changes to laws, regulations or guidance from regulatory entities 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. The FDA has recently adopted new guidance related to issues associated with product development, such as sterilization and packaging of products, which may adversely affect regulatory clearances that we are currently seeking or the timing of those regulatory clearances, and may adversely affect regulatory clearances or approvals that we seek in the future. Any new regulations or guidance or revisions or reinterpretations of existing regulations or guidance may impose additional costs or lengthen review times of our products or affect our ability to obtain clearance or approval of our new 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.

If Congress repeals, replaces or changes the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 or, collectively, the PPACA or Affordable Care Act, the Affordable Care Act or otherwise implements certain health care reforms that have been proposed, we could be subject to a regulatory and reimbursement scheme that has a material impact on our business. The Affordable Care Act changed how some healthcare providers are reimbursed by the Medicare program and some private third-party payors. Upon taking office, President Trump signed an executive order directing federal agencies to avoid enforcement of any provision of the PPACA. An initial version of proposed legislation designed to repeal the PPACA, and replace it with a system of tax credits and dissolve an expansion of the Medicaid program was not adopted by Congress. Recent spending bills passed by Congress have made some changes to the PPACA. Although the previously proposed legislation intended to repeal or significantly restructure the PPACA has not had sufficient support to pass Congress, there is a continued focus on and uncertainty regarding the future of the current PPACA framework. Changes to the PPACA, adoption of the American Health Care Act or other legislative and regulatory changes in the health care field could adversely affect our business, including by decreasing the number of patients in the United States with health insurance, reducing the amount of funds currently available to patients as a result of repeal of significant portions of the PPACA, eliminating and/or reducing programs (such as the Comprehensive Care for Joint Replacement program) that are potentially beneficial to us, reducing the amount of funds available for procedures performed in outpatient and ambulatory care facilities, or the adoption of other changes in health care regulation and reimbursement that have been proposed or that may be proposed.

The recent presidential and congressional elections may lead to amendments or repeals of all or portions of existing health care reform legislation, including the Patient Protection and Affordable Care Act. 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. Changes in existing health care reform measures may result in uncertainty with respect to legislation, regulation and government policy that could significantly impact our business and the medical device industry.

Risks related to other legal and compliance matters

We have been 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.

We have been subject to securities class actions in the past, and there may be additional suits or proceedings brought in the future related to our voluntary recall of specific serial numbers of patient-specific instrumentation for our iUni, iDuo, iTotal CR and iTotal PS knee replacement product systems. Monitoring and defending against legal actions, whether or not meritorious, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities, and we cannot predict how long it may take to resolve such matters. In addition, we may incur substantial legal fees and costs in connection with litigation. Although we have insurance, coverage could be denied or prove to be insufficient. The substantial costs and diversion of management's attention in any such litigation could harm our business and a decision adverse to our interests in any such lawsuit could result in the payment of substantial damages and could have a material adverse effect on our business, results of operations and financial condition.

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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 through 2019. 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. On January 22, 2018, legislation was passed that suspends the medical device excise tax for sales in 2018 and 2019. The tax is not scheduled to take effect again until sales on or after January 1, 2020. It is unclear at this time if the suspension will be further extended, and we are currently subject to the tax after December 31, 2019. 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; 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 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, HIPAA 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.

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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;
- issuance of additional shares of our common stock related to raising capital for the Company;
- actual or perceived need of the Company to raise additional capital and the actual or perceived inability to raise such capital on favorable terms;

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- actual or perceive inability of the Company to satisfy the financial and other requirements of our 2017 Secured Loan Agreement;
- our ability to develop, obtain regulatory approval for and market new and enhanced products on a timely basis;
- changes in coverage and reimbursement policies by insurance companies and other third-party payors;
- our commencement of, or involvement in, litigation;
- additions or departures of key management or technical personnel; and
- changes in laws or governmental regulations applicable to us.

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

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

- seasonality in demand for our products, with reduced 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 number of cancelled sales orders and surgical cases using our implants that occur in a quarter or during other reporting periods, which may adversely affect our product margins, revenue and other aspects of our business;
- 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.

Some 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 and other substantial sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

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

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

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

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

Our executive officers, directors and principal stockholders and their affiliates beneficially own in the aggregate, shares representing approximately 50.38% of our capital stock as of December 31, 2017. 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, 2017, we had federal net operating loss, or NOL, carryforwards of $374 million and state NOL carryforwards of $199 million available to reduce future taxable income. These federal and state NOL carryforwards will begin to expire in 2018, 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 revenue of $1.07 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

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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. These requirements may result in significant legal and financial compliance costs and make some activities more time-consuming and costly. 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 are required to furnish a report by our management on our internal control over financial reporting in our Annual Reports 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 comply with SOX Section 404, we document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have and 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, we may identify one or more material weaknesses, which 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 Billerica and Wilmington Massachusetts and Wallingford Connecticut. We occupy approximately 45,000 square feet of office space in Billerica, Massachusetts under a lease that expires in October 2025. We occupy approximately 59,000 square feet of manufacturing space in Wilmington, Massachusetts under a lease that expires in April 2021. On August 9, 2017, we entered into a lease for

4,099 square feet of space in Wallingford, CT which houses our polishing facility. The lease term is five years with options to extend for two additional years beyond the original term and an additional three years past the first extension term.

ITEM 3. LEGAL PROCEEDINGS

In the ordinary course of our business, we are subject to routine risk of litigation, claims and administrative proceedings on a variety of matters, including patent infringement, product liability, securities-related claims, and other claims in the United States and in other countries where we sell our products.

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, and we amended our complaint on June 13, 2016 (the "Smith & Nephew Lawsuit"). The Smith & Nephew Lawsuit alleges that Smith & Nephew’s Visionaire® patient-specific instrumentation as well as the implants systems used in conjunction with the Visionaire instrumentation infringe nine of our patents, and it requests, among other relief, monetary damages for willful infringement, enhanced damages and a permanent injunction.

On May 27, 2016, Smith & Nephew filed its answer and counterclaims in response to our lawsuit, which it subsequently amended on July 22, 2016. Smith & Nephew denied that its Visionaire® patient-specific instrumentation as well as the implants systems used in conjunction with the Visionaire instrumentation infringe the patents asserted by us in the lawsuit. It also alleged two affirmative defenses: that the patents we asserted are invalid and that we are barred from relief under the doctrine of laches. In addition, Smith & Nephew asserted a series of counterclaims, including counterclaims seeking declaratory judgments that Smith & Nephew’s accused products do not infringe our patents and that our patents are invalid. Smith & Nephew also alleged that ConforMIS infringes ten patents owned or exclusively licensed by Smith & Nephew: two of those patents Smith & Nephew alleges are infringed by our iUni and iDuo products; three of those patents Smith & Nephew alleges are infringed by our iTotal products; and five of those patents Smith & Nephew licenses from Kinamed, Inc. of Camarillo, California and alleges are infringed by our iUni, iDuo and iTotal products. Due to Smith & Nephew’s licensing arrangement with Kinamed, Kinamed was named as a party to the lawsuit. Smith & Nephew and Kinamed requested, among other relief, monetary damages for willful infringement, enhanced damages and a permanent injunction. On March 9, 2017, the Court entered a stipulation of dismissal by the parties that dismissed from the lawsuit eight patents asserted by Smith & Nephew, including the patents involving Kinamed, and two patents asserted by us.

Between September 21, 2016 and March 1, 2017, Smith & Nephew filed sixteen petitions with the United States Patent & Trademark Office (“USPTO”) requesting Inter Partes Review of the nine patents that we asserted against Smith & Nephew in the lawsuit. In its petitions, Smith & Nephew alleged that our patents are obvious in light of certain prior art. As of October 31, 2017, the USPTO decided to institute IPR proceedings with respect to seven of the petitions; decided to deny the requests for IPR with respect to seven of the petitions; and, with respect to the remaining two petitions, decided to institute IPR proceedings for certain of the subject patent claims and to deny the requests for the remaining subject patent claims. In total, the USPTO instituted IPR proceedings for some or all of the subject patent claims in six of the patents in the Smith & Nephew lawsuit (five patents that are currently asserted, and one of the patents that was voluntarily dismissed from the lawsuit), and denied the petitions for all subject claims in three of the patents (two patents that are currently asserted and one of the patents that was voluntarily dismissed from the lawsuit). Smith & Nephew filed requests for rehearing in three of the petitions that were either partially or completely denied and filed requests for reexamination of two of the patents for which no IPR was instituted. The requests for rehearing were denied.

On January 27, 2017, Smith & Nephew filed a motion seeking a stay of the Smith & Nephew Lawsuit until any requested IPRs are resolved, and we filed an opposition to that motion. On April 27, 2017, the Court stayed certain aspects of the proceedings and indicated that it will make a final decision on the motion to stay after the USPTO has decided more of the petitions for IPR. We are presently unable to predict the outcome of the motion to stay the proceedings, the instituted IPRs, the reexaminations, or the Smith & Nephew Lawsuit or to reasonably estimate a range of potential losses, if any, related thereto. An adverse outcome of some or all of the IPR proceedings, the reexaminations, and the Smith & Nephew Lawsuit could have a material adverse effect on our business, financial

condition or results of operations.

For further information regarding such legal proceedings, see the section entitled “Legal Proceedings” of “Note J-Commitments and Contingencies” in this Annual Report on Form 10 -K.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

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ITEM 5. MARKET FOR 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
Year ended December 31, 2016:		
First Quarter	$17.35	$7.55
Second Quarter	$13.83	$4.80
Third Quarter	$10.00	$6.62
Fourth Quarter	$10.93	$6.66
Year ended December 31, 2017:		
First Quarter	$8.72	$4.35
Second Quarter	$5.98	$3.79
Third Quarter	$5.73	$3.22
Fourth Quarter	$4.17	$2.22

Holders of Our Common Stock

As of February 28, 2018, there were approximately 187 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, 2017. 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

On August 9, 2017, we entered into an Asset Purchase Agreement with Broad Peak Manufacturing, LLC under which we issued 169,096 shares of our unregistered common stock to BPM having an approximate value of $0.6 million as of the closing date. The issuance of this stock consideration was not registered under the Securities Act.

Use of Proceeds from Registered Securities

In January 2017, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on May 9, 2017 (the “Shelf Registration Statement”). The Shelf Registration Statement allows us to sell from time to time up to $200 million of common stock, preferred stock, debt securities, warrants, or units comprised of any combination of these securities, for our own account in one or more offerings. On May 10, 2017, we filed with the SEC a prospectus supplement (the “Prospectus Supplement”), for the sale and issuance of up to $50 million of our common stock and entered into a Distribution Agreement with Canaccord Genuity, pursuant to which Canaccord has agreed to sell shares of our common stock from time to time, as our agent in an “at-the-market” offering ("ATM") as defined in Rule 415 promulgated under the Securities Act . We are not obligated to sell any shares of our common stock under the Distribution Agreement. As of December 31, 2017, we sold 228,946 Shares under the Distribution Agreement resulting in net proceeds of $1.0 million.

On January 29, 2018, we closed an offering of our common stock off of the Shelf Registration Statement and issued and sold 15,333,333 shares of our common stock (including 2,000,000 shares of common stock issued in connection with the exercise in full by the underwriters of their over-allotment option) at a public offering price of $1.50 per share, for aggregate net proceeds of approximately $21.3 million, For further information regarding this public offering, see "Note R - Subsequent Events - 2018 Common Stock Offering" in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

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, 2017 and 2016 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, 2015 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)	2017	2016	2015
Consolidated statements of operations data:			
Revenue	$78,115	$79,899	$66,887
Cost of revenue	49,301	53,192	45,102
Gross profit	28,814	26,707	21,785
Operating expenses:			
Sales and marketing	38,788	41,086	37,558
Research and development	17,136	16,608	16,997
General and administrative	28,737	25,157	23,191
Total operating expenses	84,661	82,851	77,746
Loss from operations	(55,847)	(56,144)	(55,961)
Other income and expenses			
Interest income	491	487	138
Interest expense	(2,119)	(138)	(1,385)
Loss on extinguishment of debt	—	—	(205)
Foreign currency transaction income (loss)	4,057	(1,607)	—
Other income (expense), net	—	(123)	208
Total other income/(expenses), net	2,429	(1,381)	(1,244)
Loss before income taxes	(53,418)	(57,525)	(57,205)
Income tax provision	162	63	41
Net loss	$(53,580)	$(57,588)	$(57,246)
Net loss per share applicable to common stockholders—basic and diluted	$(1.24)	$(1.39)	$(2.60)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	43,343,459	41,521,629	21,993,066

	December 31,		
(in thousands)	2017	2016	2015
Consolidated balance sheet data:			
Cash and cash equivalents	$18,348	$37,257	$117,185
Investments	26,880	28,242	—
Working capital	56,942	81,577	132,894
Total assets	93,798	112,810	157,099
Long term debt, including current portion	29,667	—	478
Total stockholders' equity	46,513	94,055	141,212

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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 $17.5 billion annually and growing, and we believe our iFit technology platform is applicable to all major joints in this market. We offer 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 50,000 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 off-the-shelf implants. In March 2016, we initiated the broad commercial launch of iTotal PS, our posterior-stabilized total knee replacement implant which addresses the largest segment of the knee replacement market.

Our iFit technology platform comprises three key elements:

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

- iFit Printing, a three-dimensional, or 3D, printing technology that we use to manufacture iJigs and that we may extend to 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 off-the-shelf implants.

All of our joint 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.

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, Hong Kong, Malaysia and Monaco. In order for surgeons to use our products, the medical facilities where these surgeons treat patients typically require us to enter into

pricing agreements. The process of negotiating a pricing agreement 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.

Cost of revenue

We produce our computer-aided designs, or CAD, in-house and in India and use them to direct all of our product manufacturing efforts. We manufacture all of our patient-specific instruments, or iJigs, tibial trays used in our total knee implants, and polyethylene tibia tray inserts for our iTotal CR, and starting in December 2017, for our iTotal PS product, in our facilities in Wilmington, Massachusetts. Also starting in December 2017, we passivate our tibial trays used in our total and partial knee products in our facilities in Wallingford, Connecticut. 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.

On August 9, 2017, we entered into an Asset Purchase Agreement, or APA, with BPM, which had been providing substantially all of the polishing services for the femoral implant components of our products. Subsequent to the BPM acquisition, we also began to passivate our tibial trays in our facilities in Wallingford, Connecticut.

Under the APA, we acquired certain specified assets and assumed certain specified liabilities of BPM, including, among other things, machining and polishing equipment, supplies, and other assets used in BPM's polishing services business. Under the APA, BPM received a $3.54 million cash payment and approximately $0.75 million (169,096 shares) of unregistered Company common stock based on the average closing value of our common stock for the 30-day trading period ending on August 9, 2017, which had a market value of approximately $0.6 million at closing. In addition, and subject to the terms and conditions of the APA, BPM may receive two earn-out payments: an additional $0.91 million retention earn-out payable in cash based on criteria tied to certain employee retention by us, and a value earn-out of up to approximately $1.3 million in cash payable on August 9, 2018 (the first anniversary of the transaction), based on the performance of the polishing business during that period. BPM, may earn up to an additional $0.65 million in cash upon exceeding certain cost targets, based on the future performance of the polishing business through August 9, 2018.

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

We expect our gross margin from the sale of our products, which excludes royalty revenue, to expand over time to the extent we are successful in reducing our manufacturing costs per unit and increasing our manufacturing efficiency as sales volume increases. We believe that areas of opportunity to expand our gross margin 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;
- obtaining more favorable pricing of certain component of our products manufactured for us by third parties;
- 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
- expanding our CAD labor in India, which we believe will reduce labor costs required to design our products.

We continue to explore the application of our 3D printing technology to select metal components of our products, which we believe may be a future opportunity for reducing our manufacturing costs. We also continue to explore other opportunities to reduce our manufacturing costs. However, these and the above opportunities may not be realized. In addition, our gross margin may fluctuate from period to period.

Operating expenses

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

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

may fluctuate from period to period due to the seasonality of our revenue and the timing and extent of our expenses.

Research and development. Research and development expense consists primarily of personnel costs, including salary, employee benefits and stock-based compensation for personnel employed in research and

development, regulatory and clinical areas. Research and development expense also includes costs associated with product design, product refinement and improvement efforts before and after receipt of regulatory clearance, development prototypes, testing, clinical study programs and regulatory activities, contractors and consultants, and equipment and software to support our development. As our revenue increases, we will also incur additional expenses for revenue share payments to our past and present scientific advisory board members, including one of our directors. 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, and facilities expense. We expect our general and administrative expense will increase in absolute dollars as we increase our headcount and expand our infrastructure to support growth in our business and our operations as a public company. As 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.

Total other income (expense), net

Total other income (expense), net consists primarily of interest expense and amortization of debt discount associated with our term loans outstanding during the year and realized gains (losses) from foreign currency transactions. The effect of exchange rates on our foreign currency-denominated asset and liability balances 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.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Tax Act") was signed into law and, as a result, the U.S. federal statutory corporate tax rate was lowered from 35% to 21% and imposes a one-time transition tax on unremitted foreign earnings on foreign subsidiaries. The Company has remeasured its deferred tax positions as of December 31, 2017 at the new enacted tax rate, resulting in a decrease to deferred tax assets in 2017 in the amount of $48.5 million. Since the Company has a valuation allowance on its deferred tax assets, there is no impact on current tax expense. For deferred taxes purposes, the Company recorded a benefit of approximately $19,000 due to the revaluation of the deferred tax liability hanging credit. The Company recorded no other material items as a result of the Tax Act. U.S. Treasury regulations and administrative guidance have not been finalized as of the date of this Form 10-K. As a result, this amount may be subject to material changes in future reporting periods. The Company will continue to review the impact of the tax bill.

Consolidated results of operations

Comparison of the years ended December 31, 2017 and 2016

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

	2017		2016		2017 vs 2016	
Years Ended December 31,	Amount	As a% of Total Revenue	Amount	As a% of Total Revenue	$ Change	% Change
Revenue						
Product revenue	$77,100	99 %	$78,921	99 %	$(1,821)	(2)%
Royalty	1,015	1	978	1	37	4
Total revenue	78,115	100	79,899	100	(1,784)	(2)
Cost of revenue	49,301	63	53,192	67	(3,891)	(7)
Gross profit	28,814	37	26,707	33	2,107	8
Operating expenses:						
Sales and marketing	38,788	50	41,086	51	(2,298)	(6)
Research and development	17,136	22	16,608	21	528	3
General and administrative	28,737	37	25,157	31	3,580	14
Total operating expenses	84,661	108	82,851	104	1,810	2
Loss from operations	(55,847)	(71)	(56,144)	(70)	297	1
Total other income/(expenses), net	2,429	3	(1,381)	(2)	3,810	276
Loss before income taxes	(53,418)	(68)	(57,525)	(72)	4,107	7
Income tax provision	162	—	63	—	99	157
Net loss	$(53,580)	(69)%	$(57,588)	(72)%	$4,008	7 %

Product revenue. Product revenue was $77.1 million for the year ended December 31, 2017 compared to $78.9 million for the year ended December 31, 2016, a decrease of $1.8 million or 2%, due principally to decreased sales of our partial knee products and decreased sales of our iTotal CR in Germany, offset by increased sales of our iTotal PS.

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

	2017		2016		2017 vs 2016	
Years Ended December 31,	Amount	As a % of Product Revenue	Amount	As a % of Product Revenue	$ Change	% Change
United States	$64,390	84 %	$62,366	79 %	$2,024	3 %
Germany	11,217	14	14,701	19	$(3,484)	(24)
Rest of world	1,493	2	1,854	2	(361)	(19)
Product revenue	$77,100	100 %	$78,921	100 %	$(1,821)	(2)%

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 84% for the year ended December 31, 2017 compared to 79% for the year ended December 31, 2016. We believe the higher level of revenue

as a percentage of product revenue inside the United States in 2017 was due to the introduction of the iTotal PS in the United States, coupled with the change in the reimbursement of our iUni and iDuo partial implants and continued weakness in our iTotal CR business in Germany.

Cost of revenue, gross profit and gross margin. Cost of revenue was $49.3 million for the year ended December 31, 2017 compared to $53.2 million for the year ended December 31, 2016, a decrease of $3.9 million or 7%. The decrease was due primarily to cost reductions from our vertical integration efforts and a decrease in production and personnel costs associated with the decrease in product revenue. Gross profit was $28.8 million for the year ended December 31, 2017 compared to $26.7 million for the year ended December 31, 2016, an increase of $2.1 million or 8%. Gross margin was 37% for the year ended December 31, 2017 compared to 33% for the year ended December 31, 2016, an increase of 400 basis points.

Sales and marketing. Sales and marketing expense was $38.8 million for the year ended December 31, 2017 compared to $41.1 million for the year ended December 31, 2016, a decrease of $2.3 million or 6%. The decrease was due primarily to a $2.4 million decrease in sales and marketing salaries and benefits, a $0.6 million decrease in travel and a $0.4 million decrease in instrumentation costs, offset by an increase of $0.6 million in sales commissions and an increase of $0.4 million in consulting fees and other expenses.

Research and development. Research and development expense was $17.1 million for the year ended December 31, 2017 compared to $16.6 million for the year ended December 31, 2016, an increase of $0.5 million or 3%. The increase was due to an increase of $0.7 million in salaries and benefits and an increase of $0.2 million in revenue share expense, offset by a decrease of $0.4 million in consulting fees.

General and administrative. General and administrative expense was $28.7 million for the year ended December 31, 2017 compared to $25.2 million for the year ended December 31, 2016, an increase of $3.6 million or 14%. The increase was due primarily to a $1.6 million increase in litigation and general legal costs, an increase of $1.5 million in salaries and benefits, asset impairment charges of $1.1 million, an increase of $0.7 million in facility costs, an increase of $0.4 million in insurance costs, and an increase of $0.2 million in software expense, offset by a $0.8 million decrease in consulting services expense, a $0.6 million refund of previously paid medical device excise tax, a decrease of $0.2 million in freight costs and a decrease of $0.2 million in bad debt expense.

Total other income/(expenses), net. Total other income/(expenses), net was $2.4 million for the year ended December 31, 2017 compared to $(1.4) million for the year ended December 31, 2016, a change of $3.8 million, or 276%. The change was primarily due to $4.1 million in foreign exchange transaction gain in 2017 compared to $1.7 million foreign exchange transaction loss in 2016, which was attributable to the effect of exchange rate change on intercompany debt with our foreign subsidiaries no longer considered permanent investments, offset by an increase of $2.0 million in interest expense associated with our long-term debt.

Income taxes. Income tax provision was $162,000 for the year ended December 31, 2017 and $63,000 for the year ended December 31, 2016. 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.

On December 22, 2017 the Tax Cuts and Jobs Act (the "Tax Act") was signed into law and, as a result, the U.S. federal statutory corporate tax rate was lowered from 35% to 21%. The Company has remeasured its deferred tax positions as of December 31, 2017 at the new enacted tax rate, resulting in a decrease to deferred tax assets in 2017 in the amount of $48.5 million. Since the Company has a valuation allowance on its deferred tax assets, there is no impact on current tax expense and for deferred taxes purposes results in a benefit of approximately $19,000 due to the revaluation of the deferred tax liability hanging credit. The Company recorded no other material items as a result of the Tax Act. U.S. Treasury regulations and administrative guidance have not been finalized as of the date of this Form 10-K. As a result, this amount may be subject to material changes in future reporting periods. The Company will continue to review the impact of these limitations as regulatory guidance is issued.

Comparison of the years ended December 31, 2016 and 2015

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

	2016		2015		2016 vs 2015	
Years Ended December 31,	Amount	As a% of Total Revenue	Amount	As a% of Total Revenue	$ Change	% Change
Revenue						
Product revenue	$78,921	99 %	$62,791	94 %	$16,130	26 %
Royalty	978	1	4,096	6	(3,118)	(76)
Total revenue	79,899	100	66,887	100	13,012	19
Cost of revenue	53,192	67	45,102	67	8,090	18
Gross profit	26,707	33	21,785	33	4,922	23
Operating expenses:						
Sales and marketing	41,086	51	37,558	56	3,528	9
Research and development	16,608	21	16,997	25	(389)	(2)
General and administrative	25,157	31	23,191	35	1,966	8
Total operating expenses	82,851	104	77,746	116	5,105	7
Loss from operations	(56,144)	(70)	(55,961)	(84)	(183)	—
Total other income/(expenses), net	(1,381)	(2)	(1,244)	(2)	(137)	(11)
Loss before income taxes	(57,525)	(72)	(57,205)	(86)	(320)	(1)
Income tax provision	63					