Conformis Inc
Form 10-K
March 13, 2019

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, 2018

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	Smaller reporting company	x
		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 $63,366,909. As of February 28, 2019 there were 67,916,658 shares of the registrant's Common Stock, $0.00001 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, 2018. 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;
- 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;
- our ability to continue as a going concern; 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 $18.1 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 90,000 knee implants, including more than 70,000 total knee implants and 20,000 partial knee implants. In multiple clinical studies, iTotal CR, our cruciate-retaining total knee replacement implant and best-selling product, demonstrated superior clinical outcomes, including better function, including kinematics and objective functional measures, and greater patient satisfaction compared to those off-the-shelf implants that it was tested against. 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. On July 31, 2018, our first Conformis Hip Systems were implanted. We are in limited commercial launch with the Conformis Hip System and intend to enter full commercial launch in the second half of 2019.

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 joint replacement implants offer significant benefits to patients, surgeons and hospitals and other medical facilities 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 joint 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 implants to follow the particular shape and contour of the patient's joint. As a result, we believe our implants offer an increased potential for a knee or hip 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 or hip replacement.

A study of 63 knee replacement surgeries, utilizing our iTotal CR total knee replacement system, published in 2017 in the peer-reviewed Journal of Knee Surgery, or 2017 JOKS, 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. At the time the 2017 JOKS Study was conducted, one of the authors of this study

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was a paid consultant to us. 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. A study published in May 2018 in The Journal of Knee Surgery, a peer-reviewed orthopedic journal, entitled "In Vivo Tibial Fit and Rotational Analysis of a Customized, Patient-Specific TKA versus Off-the-Shelf TKA," indicated that the iTotal CR knee replacement implant provided better rotational alignment and tibial fit compared to off-the-shelf implants (i.e., non-customized). We provided financial support for this study and the author is a paid consultant of ours on other matters. In addition, in a January 2019 report from Beyond Compliance, results were presented summarizing four year data from the England and Wales National Joint Registry ("Registry") demonstrating high survivorship in patients treated with the iTotal CR knee replacement implant, specifically the data showed a low cumulative percent revision of 1.4% for Conformis patients as compared with 1.9% for all total knee replacement patients.

- For the surgeon. We believe that the combination of the use of our pre-surgical plan, or iView, and patient-specific iJigs with our customized joint 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. With regard to our Conformis Hip System, our pre-operative surgical plan, or Hip iView, provides anatomical information to surgeons in advance of surgery that is not available today through the use of standard templating tools. In addition, surgeons have input into our hip system designs within a defined range of parameters to allow surgeons to optimize the Conformis Hip System for each patient, including allowing for leg length correction. An acetabular positioning iJig is used to place the acetabular cup in the position which is intended to maximize anatomical coverage of the cup, with the goal of eliminating the need for intra-operative navigation and also reducing or eliminating surgeon exposure to fluoroscopy. Our novel acetabular reaming system interacts with the acetabular iJigs to ream only to a predetermined depth, thereby reducing inadvertent punctures of the pelvis, in a reduced number of procedural steps.
- For the hospital, ambulatory surgical center or other medical facility. Our hip and knee replacement joint products are delivered directly to the surgery center in a single, sterile, patient-labeled kit, eliminating the need for surgery centers to stock excess inventory for each surgical procedure. Unlike off-the-shelf systems for both knee and hip, our systems require little to no re-useable instrumentation due to the use of 3D printed iJigs as well as 3D printed intra-operative sizing trials. This eliminates or reduces the quantity of re-useable instruments and trays that must be processed through the facility to support each surgical procedure, which is especially important for ambulatory surgical centers, and reduces per case cost and also the potential risk for infection. Operating room set up time is also reduced due to the limited number of instruments needed which supports the ability to complete more surgical cases in a given day. We believe that our customized joint replacement implants and iFit technology platform provide a better economic outcome for hospitals or other medical facilities 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 or other medical facility to generate additional revenue.
- For the payor. We believe that our individualized approach offers better clinical outcomes when compared to off-the-shelf implants which leads to faster patient recoveries and lower costs for payors.

As of February 28, 2019, we own or exclusively in-license a total of approximately 358 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 157 issued United States patents, 85 patents issued in countries outside the United States, and 116 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, Austria, Ireland, Switzerland, Singapore, Hong Kong, Malaysia, Monaco, Hungary, Spain, Australia 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 2017 calendar year, which was published in May 2018 by Orthoworld Inc., or the 2017 Orthoworld Report, worldwide sales of joint replacement products, including replacements for knees, hips, shoulders, elbows, wrists, ankles and digits outside of trauma, exceeded $18.1 billion in 2017 and are expected to grow to approximately $21.7 billion by the end of 2022. The 2017 Orthoworld Report estimated that worldwide sales of knee replacement products totaled approximately $8.8 billion and, according to Smart Track, the United States represented approximately 48% of total estimated worldwide sales of such products. In 2017, according to the 2017 Orthoworld Report, worldwide sales of hip replacement products totaled approximately $7.2 billion. According to the 2017 Orthoworld Report, 2017 estimated sales of hip replacement products in the United States represented approximately 40% of total estimated worldwide sales of such products. According to Smart Trak, primary total hip replacement implants accounted for approximately 69% by revenue of the 2017 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 2017 Orthoworld Report, the worldwide extremities joint replacement market was estimated at $2.1 billion in 2017.

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:

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- 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 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 replacement implant and iJigs to the hospital or other medical facility 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 joint replacement implants offer significant benefits to patients, surgeons and hospitals or other medical facilities 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 and hip implants to restore the patient's own native anatomy. As a result, we believe that our implants fit better and regain better function, 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 anatomy to provide a more stable, natural feeling joint. With regard to our knee implant products, we 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.

- 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 and hip replacements.

- Earlier intervention. We believe that patients who undergo knee and hip replacement with one of our products typically retain more of their bone during the surgical procedure, as compared to patients who undergo knee or hip 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 or hip 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 and hip 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 and hip 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

knee replacement 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 bone or soft tissue. In our hip replacement procedure, the surgeon receives our pre-operative surgical plan, or Hip iView, that provides anatomical information in advance of surgery that is not available today through the use of standard templating tools. In addition, surgeons have input into our hip system designs within a defined range of parameters to allow surgeons to optimize the Conformis Hip System for each patient, including allowing for leg length correction. Our novel acetabular reaming system interacts with the acetabular iJigs to ream only to a predetermined depth, thereby reducing inadvertent punctures of the pelvis, in a reduced number of procedural steps. An acetabular positioning iJig is used to place the acetabular cup in the position which is intended to optimize anteversion, inclination and anatomical bone coverage of the cup, which we believe will eliminate the need for intra-operative navigation, and also the use of fluoroscopy during the procedure, reducing radiation exposure for both the patient and the surgical staff.

- 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 our knee or hip system as compared to off-the-shelf implants. 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. We also believe the Conformis Hip System will provide reduced operating times as compared to off-the-shelf implants based on both the implant sizing provided to the surgeon in the Hip iView as well as our novel reaming

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system. Thus far in our limited launch of the Conformis Hip System, surgeons have reported reduced operating time as compared to off-the-shelf hip implants.

- For the hospital, ambulatory surgical center or other medical facility. We believe that our customized implants and iFit technology platform provide a better economic outcome for hospitals or other medical facilities through:

Improved implant and instrument management and reduced sterilization costs. As a result of our just-in-time delivery model, we ship our knee and hip 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 or other medical facility. Our hip and knee replacement joint products are delivered directly to the surgery center in a single, sterile, patient-labeled kit, eliminating the need for surgery centers to stock excess inventory for each surgical procedure. Unlike off-the-shelf systems for both knee and hip, our systems require little to no re-useable instrumentation due to the use of 3D printed iJigs as well as 3D printed intra-operative sizing trials. We estimate that a total knee replacement procedure using an off-the-shelf implant requires approximately 6 to 8 double-tiered, instrument trays and a hip replacement procedure using an off-the-shelf implant requires approximately 5 to 7 double-tiered instrument trays, which must be cleaned, sterilized and stored between procedures at significant cost to the hospital or other medical facility. A knee replacement procedure using our iTotal CR product requires only one tray of reusable instruments and a hip replacement procedure using our Conformis Hip System uses only 2 trays 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 off-the-shelf implants, we believe our products meaningfully reduce a hospital's or other medical facility’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 off-the-shelf products. 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 and hip replacements with our customized knee and hip implants can improve turnaround times with the potential for more procedures to be completed within the same amount of time and for hospitals or other medical facilities to generate additional revenue.

- Shorter stays. We believe that our customized total joint replacements may shorten hospital or other medical facility 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 ($p\leq0.05$) 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 or other medical facilities and payors. For example, the 2017 AT Study compared adverse events rates and cost of care for total knee arthroplasty patients treated with either customized individually made implants or off-the-shelf implants. In that study, the total average real hospital costs between the customized implant and off-the-shelf 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 $914 per patient for the customized implant group for bundle of care, including the preoperative computed tomography scan, total knee arthroplasty hospitalization, and discharge disposition. Follow-up care costs demonstrated a savings of $1,313 per patient. Additionally, a retrospective study that we funded, reviewed over 4,000 Medicare patients who had undergone total knee replacement, was published in the peer-reviewed journal Orthopaedic Proceedings in October 2018, indicated that the cost of care over a 12 month total episode of care was, on average, $1,697 lower for patients who received our customized implants compared to

patients who received off-the-shelf total knee implants.

Fewer adverse events. Many insurers and third-party payors, including Medicare, require the hospital or other medical facility 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 and hip 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 or other medical facilities 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 implant products offer important clinical and economic benefits to patients, surgeons and hospitals or other medical facilities. 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 or other medical facilities 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/individualized orthopedic implants and complementary non-individualized 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 2017, we received clearance from the FDA for the Conformis Hip System, our first customized hip replacement implant, which we launched on a limited basis in the second half of 2018 and are planning a full commercial launch in the second half of 2019. We expect a limited commercial launch of a second stem for the Conformis Hip System in the second half of 2020 with a full commercial launch in the second half of 2021. We anticipate a limited commercial launch of our next generation iTotal CR knee replacement implant in the second half of 2019 followed by a full commercial launch for both the iTotal CR and PS knee replacement implants in the second half of 2020. We have put the development of the next generation of our iUni partial knee replacement system on hold in order to focus on an iTotal cementless option for our iTotal knee implant. We now anticipate a limited commercial launch of the next generation iUni in the first half of 2021. We intend to have a limited commercial launch of a femur cementless or Press Fit option for our iTotal knee implant in the first half of 2020 with a full commercial launch in the first half of 2021. We expect to have a limited commercial launch of a tibia cementless or Press Fit option n the first half of 2021. 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 and spine.

- 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 the difficulty faced by our competitors of making obsolete a large inventory of off-the-shelf implants and instruments;

- Enhance our patent portfolio and continue to exploit our patent position. As of February 28, 2019, we own or exclusively in-license a total of approximately 358 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 or other medical facility 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 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 tibia tray 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 introduced the iTotal PS in 2015. The iTotal PS includes a femoral implant with a metal cam, a tibial tray, and a single polyethylene tibia tray insert, which includes a plastic spine, all of which are individually made for the particular patient, together with a polyethylene patella designed to work with our customized components.

The iDuo is the only customized bicompartmental knee replacement system on the market. The iDuo is considered a bicruciate-retaining knee replacement because the surgeon may retain both the anterior cruciate ligaments, or ACL, and posterior cruciate ligaments, or PCL. We introduced the iDuo in 2007 and launched a second generation in 2010. The iDuo includes a femoral implant, a tibial tray and a single polyethylene tibia tray 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 a customized unicompartmental knee replacement product for treatment of the medial or lateral compartment of the knee. The iUni is considered a bicruciate-retaining knee replacement because the surgeon retains both the ACL and PCL. We introduced the iUni in 2007 and launched a second generation in 2009. The iUni includes a femoral implant, a tibial tray and a single polyethylene tibia tray 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 launched the system on a limited basis in the second half of 2018. Similar to the design process we use for our knee implant products, we use proprietary software, to design and manufacture our Conformis Hip System implants and iJigs. After each patient's CT scan is converted into a 3-dimensional computer model, the unique measurements of each patient's anatomy are transformed into a comprehensive, individualized, pre-operative surgical plan, or Hip iView, that is delivered to the surgeon in advance of the operation. The Hip iView provides anatomical information to the surgeon that is not available today through the use of standard templating tools. Surgeons have input during the planning process within a defined range of parameters to allow them to optimize the Conformis Hip System for each patient, including allowing for leg length correction. Our Conformis Hip System provides a femoral stem with a patient-specific neck and head size as well as a patient-specific acetabular cup size which, together with the Hip iView, allows for improved operating room efficiency and decreased inventory needs of the facility. In addition, our Conformis Hip System includes a novel acetabular reaming system that interacts with the acetabular iJigs to ream only to a predetermined depth in a reduced number of procedural steps. Our Conformis Hip System further includes an acetabular positioning iJig that is used to place the acetabular cup in the position which is intended to optimize anteversion, inclination and anatomical coverage of the cup, with the goal of eliminating the need for intra-operative navigation, reducing surgeon, staff and patient exposure to fluoroscopy.

As of February 28, 2019, over 25 surgeons have implanted over 200 Conformis Hip Systems. To date, surgeon feedback is confirming our expectations related to improved surgical efficiencies.

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 and knee and hip replacement implants are sold through the same distribution channels. We also believe our surgical plan and improved surgical technique for hip arthroplasty will attract surgeons who are not current customers. Thus, we believe that the Conformis Hip System complements our existing product line and will allow us to expand our customer base, sales force and distribution channels.

The following is an overview of our Conformis Hip System:

Conformis Hip System

The Conformis Hip System, introduced in July 2018, is the only primary total hip replacement system on the market designed with 3D imaging technology to provide a stem and acetabular cup size that matches each patient's specific anatomy.

The implant system includes a single-piece stem with patient-specific neck, acetabular cup, iPoly XE® (highly crosslinked vitamin-e infused UHMWPE) polyethylene liner, and a choice of ceramic or cobalt chrome femoral head.

3D imaging technology is also used to create a pre-surgical plan, which accompanies a set of disposable patient-specific 3D printed jigs, to aid in implant positioning.

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 implants enables 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. A knee replacement procedure performed using our customized implants and iJigs requires only one tray of reusable instruments, which we provide to the hospital or

other medical facility, as compared to a knee replacement procedure using an off-the-shelf implant, which requires approximately 6 to 8 double-tiered, reusable instrument trays, which the off-the-shelf manufacturer provides to the hospital or other medical facility. A hip replacement procedure performed using our customized implants and iJigs requires only 2 trays of reusable instruments, which we provide to the hospital or other medical facility, as compared to a hip replacement procedure using an off-the-shelf implant, which requires approximately 5 to 7 double-tiered, reusable instrument trays, which the off-the-shelf manufacturer provides to the hospital or other medical facility. 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, 2019, there were 27 peer-reviewed journal articles and numerous 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, Monaco, Hungary, Spain and Australia. 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 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 sales representatives to spend time in the operating room during a procedure when compared to the sales 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. In addition, we believe surgeons will appreciate the additional patient information and improved surgical efficiencies provided by our Conformis Hip System. We believe hospitals and other medical facilities, including ambulatory surgical centers, 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 other medical facilities 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. We intend to use the same commercial strategy for the Conformis Hip System.

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 28 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, 2018, 2017 and 2016, company-sponsored research and development expense was $16.9 million, $17.1 million and $16.6 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 selling the product.

Manufacturing

We conduct our manufacturing activities in state-of-the-art design and manufacturing facilities in Wilmington, Massachusetts and Wallingford, Connecticut.

We produce computer-aided designs (“CAD” or “CAD designs”) in-house and through a third party in India, and we use the CAD designs to direct a majority of our product manufacturing efforts. As part of our manufacturing cost reduction efforts, in 2017 and 2018, we continued transitioning our in-house CAD labor force to the third party in India and, in 2018, we significantly reduced our in-house CAD labor force. We manufacture all of our patient-specific instruments, or iJigs, tibial trays used in our total knee implants, polyethylene tibia tray inserts for our total knee implants, 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 in Wallingford, Connecticut. Our femoral implant components are polished and passivated at our facility 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 an 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 polymer powder used for 3D printing our iJigs and the polyethylene block used for CNC machining of our tibia tray inserts, 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;

- 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;

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- continue to transition our in-house CAD labor force to 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 patient-specific instruments. As a result, 3D printing plays a key role in our manufacturing operations.

We 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.

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, 2019, we owned or exclusively in-licensed 242 issued patents around the world, including 157 patents issued in the United States and 85 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 2031.

- 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 2035.

- 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, 2019, we owned or exclusively in-licensed 116 patent applications, including 24 patent applications pending in the United States and 92 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

See Part II, Item 3, Legal Proceedings of this Annual Report on Form 10-K.

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 2031.

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 2027.

License agreement with Smith & Nephew

In September 2018, we entered into a worldwide license agreement with Smith & Nephew. Under the terms of this agreement, we granted a perpetual, irrevocable, non-exclusive license to Smith & Nephew to use patient-specific instrument technology covered by our patents and patent applications with off-the-shelf implants. With respect to knee implants, Smith & Nephew agreed to pay a single lump-sum payment of $10.5 Million upon entering into the license agreement, which has been paid. Smith & Nephew also agreed to pay to us a fixed royalty at a high single to low double digit percentage of net sales on any future sales of patient-specific instruments for use with off-the-shelf implants for joints other than knees. Additionally, under this agreement, we granted a perpetual, irrevocable, non-exclusive license to Smith & Nephew to use certain knee implant technology covered by our patents and patent applications with off-the-shelf implants in the knee. Smith & Nephew granted to us a worldwide, perpetual, irrevocable, non-exclusive license to certain patents and patent applications owned by Smith and Nephew and certain patents and patent applications exclusively licensed by Smith & Nephew from Kinamed covering knee replacement implants and instruments in connection with the sale of patient-specific implants. No payment was due from us to Smith & Nephew. The rights granted by us to Smith & Nephew under this license do not extend to any uses associated with patient-specific implants, and the rights granted by Smith & Nephew to us do not extend to any uses associated with off-the-shelf implants.

Trademarks

As of February 28, 2019, we have filed 163 trademark registrations in the United States and in other major markets worldwide, including the following marks: Conformis, iFit, iTotal, iDuo, and iUni. We have 14 trademark applications pending 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 other medical facilities, third-party payors, and independent sales representatives and distributors, 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 and other medical facilities;
- 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 other medical facilities; 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 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.

Even after we have obtained the proper regulatory clearance to market a product, the FDA has the power to require us to conduct post-marketing studies. For example, as a condition of clearance or 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 for the product that is subject to such a requirement and could also result in the recall or withdrawal of our product from the market in the United States, which would prevent us from generating revenue from sales of that product in the United States.

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.

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. We have submitted for recertification of our iUni and iDuo products and plan to submit for recertification for our iTotal PS product through May 2024. 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.

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 Union regulatory bodies finalized a new Medical Device Regulation, or MDR, in 2017, which replaces the existing Directives and provided three years for transition and compliance. We must be compliant with the MDR by May 2020. The MDR will significantly change several aspects of the existing regulatory framework, such as clinical studies and data requirements and introduce new ones, such as unique device identification, post marketing clinical reports and patient identification. We and the Notified Bodies who will oversee compliance to the new MDR face uncertainties as the MDR is rolled out and enforced by the Commission and EEA Competent Authorities, creating risks in several areas, including the CE Marking process and data transparency, in the upcoming years. We expect to be compliant with the EU MDR on or before May 2020.

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 government regulation-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 and approval of use 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%. In addition to being affected by changes in reimbursement rates, use of our products for each patient in Germany may also be subject to approval by the Medizinischer Dienst der Krankenkassen (translated: Medical Service of Health Insurance), or MDK. Beginning in 2016, we experienced a significant increase in the number of denials by MDK for increased cost associated with the use of our products and, in such instances, the amount of reimbursement to the hospitals and other medical facilities was lowered to that of an off-the-shelf knee. 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. The decrease in the rate of reimbursement for surgical procedures using our iUni and iDuo products and the increasing denials by MDK for approval under the higher reimbursement code has adversely impacted our sales in Germany.

In January 2019, the rate of reimbursement for surgical procedures using our products in Germany was changed. Beginning January 1, 2019, the reimbursement for surgical procedures using our iTotal CR and iTotal PS products increased by approximately 1.6%, while the reimbursement for surgical procedures using our iUni and iDuo products increased by approximately 30%. Though this increase in reimbursement is a positive change, especially with regard to our iUni and iDuo products, we continue to experience MDK denials of the higher reimbursement code, which continues to adversely impact our sales in Germany. We are working with our physicians and hospitals and other medical facilities in Germany and experienced consultants to appeal MDK denials and demonstrate to MDK the benefits of our products, including patient satisfaction and recovery rates. In the fourth quarter of 2018, sales in Germany represented 9% of our total product sales.

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 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, 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. Enforcement of these regulations began May 25, 2018.

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, 2019, we had 268 employees, including 262 full-time employees, 40 of whom were engaged in sales and marketing, 28 in research and development, 131 in manufacturing and service, 41 in regulatory, clinical affairs and quality activities and 28 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 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

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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 continue to incur losses and may never achieve profitability.

We have incurred significant net operating losses in every year since our inception and expect to continue to incur net operating losses for the next several years. Our net loss was $43 million for the year ended December 31, 2018, $54 million for the year ended December 31, 2017 and $58 million for the year ended December 31, 2016. As of December 31, 2018, we had an accumulated deficit of $476 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 may 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, including for the expanded commercial launch of our Conformis Hip System;
- 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 sale of our products, potential future capital raises through the issuance of equity or other securities, potential debt financings and revenue that we may generate in connection with licensing our intellectual property. We will need to generate significant additional revenue to achieve and maintain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. 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, technologies or geographies 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.

We are a party to an Equity Distribution Agreement dated May 10, 2017, or the Distribution Agreement, with Canaccord Genuity Inc., or Canaccord, as sales agent, pursuant to which we may issue and sell shares of our common stock from time to time in "at-the-market" offerings. Additionally, we are a party to a purchase agreement dated December 17, 2018, or the Stock Purchase Agreement, with Lincoln Park Capital Fund, LLC, or LPC, pursuant to which we have the right, at our sole discretion, to sell to LPC up to $20 million worth of shares of our common stock. We expect to further 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, including pursuant to the Distribution Agreement and the Stock Purchase Agreement, 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.

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

On January 6, 2017, we entered into the 2017 Secured Loan Agreement with Oxford, and accessed $15 million of borrowings under Term Loan A at closing and an additional $15 million of borrowings under Term Loan B on June 30, 2017. We were unable to access an additional $20 million potentially available to borrow through June 2018 due to a failure to satisfy certain revenue milestones and customary drawdown conditions. Pursuant to a fifth amendment to the 2017 Secured Loan Agreement, or the Fifth Amendment, on December 13, 2018, we pre-paid $15 million aggregate principal amount of the $30 million outstanding principal amount, as a pro rata portion of the Term A Loan and Term B Loan, together with accrued and unpaid interest thereon and a pro rata prepayment fee. 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 our cash. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, our failure to meet defined measures of financial performance, our 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. The Fifth Amendment also reduced the revenue milestones through December 31, 2019. New minimum revenue milestones, based on product revenue projections, are to be established prior to the start of 2020 and prior to the start of each fiscal year thereafter by the mutual agreement of Oxford and us. If we are not able to agree with Oxford on new minimum revenue milestones for 2020 or a fiscal year thereafter, we must refinance the 2017 Secured Loan Agreement by March 31, 2020 or that next fiscal year, and if we fail to refinance the 2017 Secured Loan Agreement, we must notify Oxford of such default and Oxford would be permitted to exercise remedies against us and our assets in respect of such event of default, including taking control of our cash and commencing foreclosure proceedings on our other assets. As of December 31, 2018, we were not in breach of covenants under the credit facility.

The initial principal payment on the 2017 Secured Loan Agreement is due on February 1, 2020. We intend to refinance the 2017 Secured Loan Agreement before the interest only period ends and the principal repayments begin in January 2020. We may not be able to refinance or 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. If we are unable to refinance the 2017 Secured Loan Agreement before the interest only period ends or shortly thereafter, then we will be required to make principal repayments beginning in January 2020 which will require us to raise additional capital through the sale of equity and the ownership interest of our stockholders will be diluted.

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.

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 a limited commercial launch of a hip replacement product 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 a limited commercial launch of our Conformis Hip System, 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, including of our Conformis Hip System upon its full commercial launch, 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 surgeons, including curtailments due to reduced reimbursement rates, medical policy coverage denials, adoption of our competitors' products or the timing of orders by these surgeons, 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 post-marketing 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 a limited commercial launch of the Conformis Hip System, for which we received FDA clearance on June 14, 2017. However, we may not be able to successfully complete a full commercial launch of the Conformis Hip System on a timely basis, or at all. Any factors that delay the commercial 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.

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 or hip that could reduce the demand for knee or hip 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, third-party payors and independent sales representatives and distributors;
- 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, hip 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 our products' 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 or other medical facility 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 or unexpected increases in the volume of orders could result in delays in our ability to deliver products to

specification, or at all, thereby resulting in delays of surgery or loss of sales if surgeons choose to implant competitive products, significantly impacting our reputation and our ability to make commercial sales. Such delays may also lead to increases in cost of goods and shipment to meet surgery dates. 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;
- negotiate more favorable prices for the manufacture of certain components of our products that are manufactured for us by third parties;
- 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 transition our in-house CAD labor force to India;
- 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 and the need to learn a new 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 competitive 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;
- 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 or difficulty associated with scheduling and seeking reimbursement for computed tomography, or CT, scans needed to manufacture our products;
- higher cost or perceived higher cost of our products compared to competitive products; and
- the additional time commitment that may be required for surgeon training on our surgical technique.

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 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 limited commercial launch. Ongoing or future clinical studies of our products 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 other medical facilities, 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 published in Reconstructive Review in 2018, involving 360 patients for which we provided financial support, the 3.1% rate of MUA for our iTotal CR product was substantially lower than the 28.6% rate of MUA shown in these single surgeon studies. Additionally, the patients who had completed their one year follow-up in the multicenter study reported a 92% satisfaction rate. By comparison, the rate of MUA reported in a separate study of off-the-shelf implants was 4.6%. The third such study was published in the Journal of Arthroplasty 2018 and 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. In a January 2019 report from Beyond Compliance, results were presented summarizing four year data from the England and Wales National Joint Registry (“Registry”) demonstrating high survivorship in patients treated with the iTotal CR knee replacement implant, specifically the data showed a low cumulative percent revision of 1.4% for our patients as compared with 1.9% for all total knee replacement patients. However, there is no guarantee that such high survivorship rates will continue over time or that our other products will provide high survivorship. Competitors may initiate their own clinical studies which may yield data that is inconsistent with data from our funded 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. 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, 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;
- provide easy adoption by and improved surgical treatment plans for surgeons;
- satisfy the increased demands by healthcare payors, providers and patients for shorter hospital or other medical facility 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, hip 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. To contain costs, governmental healthcare programs and third-party payors are increasingly scrutinizing new and even existing treatments and technology by requiring extensive evidence of favorable clinical outcomes and cost effectiveness. Payors may view new products or products that have only recently been launched or with limited clinical data available, including our iUni, iDuo, iTotal CR, and iTotal PS knee replacement systems and the 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. 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.

We are aware of certain private insurers that at this time are not agreeing to reimburse for our products as they consider the use of custom implants or patient-specific instrumentation for knee replacement surgery as investigational, unproven or experimental or not medically necessary. While we are actively reaching out to these private insurers to discuss their reimbursement policies, we may not be able convince these parties to change their reimbursement policies. 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 believe that this is a similar situation directed to patient-specific instruments with off-the-shelf implants, not use of patient-specific instruments with custom implants. Surgeons, hospitals and other medical facilities may not purchase our products 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. 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 in the future 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, in the future, any alternative imaging technique, we could find that we have to find alternative ways to pay these costs, for example, we could pay these costs ourselves directly to the imaging facility, 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. If payors do not reimburse the costs of the CT scan and we are unable to find an alternative way to pay these costs, we may be unable to sell our products which could have a material adverse effect on our business and operations.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 or, collectively, the ACA, 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 is able to keep the savings. 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.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". The Congress will likely consider other legislation to replace elements of the ACA during the next Congressional session.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

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 and approval for use 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 in 2017, changed positively for 2019 and could further change negatively in Germany and other jurisdictions. In addition, beginning in 2016, we have seen an increase in denials of the higher reimbursement code for use of our products in Germany by the Medizinischer Dienst der Krankenkassen (translated: Medical Service of Health Insurance), or MDK, and, in such instances, the amount of reimbursement to the hospitals and other medical facilities has been lowered to that of an off-the-shelf knee.

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 or if trained surgeons do not continue to use 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 continue to use our products and 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. If trained surgeons do not continue to use our products, this could cause our revenue to decline.

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

We rely on a limited number of direct and independent sales representatives and distributors to market and sell our products. Loss of our sales representatives and distributors could harm our business.

We rely on our direct and independent sales representatives in the United States, direct sales representatives in Germany and distributors in certain other countries to market and sell our products. Our sales representatives and distributors are highly trained and possess substantial technical expertise as well as relationships with surgeons, hospitals and other medical facilities. The loss of these sales representatives or distributors to competitors or otherwise could materially harm our business. If we are unable to retain our sales representatives or distributors or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement sales representatives or distributors or such replacements are unable to develop the necessary relationships, our revenue and results of operations could be materially harmed.

If our independent sales representatives and distributors are not successful in selling our products, our sales may decline.

We depend on independent sales representatives and distributors for the marketing and sales of our products. Revenue generated from the sales of our products by independent sales representatives represented approximately 84% of our total revenue from sales of our products in the United States for the year ended December 31, 2018, approximately 78% of our total revenue from sales of our products in the United States for the year ended December 31, 2017 and approximately 71% of our total revenue from sales of our products in the United States for the year ended December 31, 2016. We do not have independent sales representatives outside

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the United States and, therefore did not generate any revenue from sales of our products by independent sales representatives outside the United States in the years ended December 31, 2018, 2017 and 2016. Revenue generated from the sales of our products to distributors represented approximately 30%, 14% and 5% of our total revenue from sales of our products outside the United States for the years ended December 31, 2018, 2017, and 2016. We did not have distributors within the United Stated and, therefore, did not generate any revenue from sales of our products to distributors in the United States in the years ended December 31, 2018, 2017 and 2016. We have entered into written agreements with 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 and, if we terminate an agreement early, we may be required to pay a fee on termination;
- 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 independent sales representatives and distributors may preclude us from entering into additional future arrangements with other independent sales representatives and distributors; and
- we may not be able to negotiate future agreements with independent sales representatives and distributors 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 also sell the products of our competitors. We cannot be certain that they will prioritize selling our products over other products they sell, including 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 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 representatives, 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 operating margins to be lower than if we directly marketed and sold our products.

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

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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.

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the EU (which is commonly referred to as “Brexit”). Thereafter, on March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the United Kingdom from the EU will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the United Kingdom provides a notice of withdrawal pursuant to the EU Treaty. Since the regulatory framework for medical devices in the United Kingdom, covering quality, safety and efficacy of medical devices, clinical trials, marketing authorization, commercial sales and distribution of medical devices is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime which applies to medical devices and the approval of medical devices in the United Kingdom. It remains to be seen how, if at all, Brexit will impact regulatory requirements for medical device candidates and medical devices in the United Kingdom.

The United Kingdom has a period of a maximum of two years from the date of its formal notification to negotiate the terms of its withdrawal from, and future relationship with, the European Union. If no formal withdrawal agreement is reached between the United Kingdom and the European Union, then it is expected the United Kingdom's membership of the European Union will automatically terminate two years after the submission of the notification of the United Kingdom's intention to withdraw from the European Union. Discussions between the United Kingdom and the European Union focused on finalizing withdrawal issues and transition agreements are ongoing. However, limited progress to date in these negotiations and ongoing uncertainty within the UK Government and Parliament sustains the possibility of the United Kingdom leaving the European Union on March 29, 2019 without a withdrawal agreement and associated transition period in place, which is likely to cause significant market and economic disruption.

We have received CE Marking for all of our products to date through the British Standards Institution, or BSI, a United Kingdom notified body. In the absence of a withdrawal agreement, BSI would no longer be recognized as a notified body for the European Union and we could not use our current CE Marks on our products when sold into the European Union. To address this concern, BSI has formed a notified body entity in the Netherlands and we are participating in a migration of our CE Marks from BSI’s United Kingdom entity to BSI’s affiliate in the Netherlands. Such migration would allow us to sell into both the European Union and the United Kingdom, as the Medicines and Healthcare Products Regulatory Agency, or MHRA, in the United Kingdom, has indicated that they would continue to accept CE Marking from European notified bodies. We believe but cannot be sure that we will complete this migration by March 29, 2019. If we are unsuccessful, it could materially impair our ability to sell our products in the European Union.

The consideration and 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. and the E.U., 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 the 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 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. Further, there may be disagreements between us and our consultants or surgeons that could lead to termination of agreements or litigation. If we are unable to establish and maintain our relationships with consultants, surgeons and medical personnel, our ability to develop and sell new and improved products could decrease, and our future operating results could be unfavorably affected.

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

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

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

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

Risks related to our manufacturing

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

We 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.

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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, vertical integration of the manufacturing process by performing machining, polishing and other finishing services in-house, and to improve internal efficiencies. We have limited commercial manufacturing experience with respect to the Conformis Hip System and no commercial manufacturing experience with respect to 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;
- managing the transition of our in-house CAD labor force to India;
- managing the oversight of the CAD labor force in India;
- acquiring and maintaining 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 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 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, polishing of our femoral components and, with regard to the hip, the stems, cups and iJigs. We outsource the manufacture of the remainder of the implant components to third-party suppliers, including, for example, the casting of the femoral component. 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 produce CAD designs, and we use the CAD designs to direct most of our product manufacturing efforts. As part of our manufacturing cost reduction efforts, in 2017 and 2018, we continued transitioning our CAD labor force through a third party CAD-designer in India and, in 2018, we significantly reduced our CAD labor force in-house. We and our suppliers, including our CAD-designer, are subject to extensive regulation by the FDA under its Quality System Regulation, or QSR. Our quality department periodically audits our suppliers, including our CAD-designer, to ensure compliance to appropriate ISO standards, FDA regulations and to our specifications, policies and procedures for our devices.

Relying on a third party for our CAD designs could harm our business for various reasons, including:

- agreement may terminate prematurely due to disagreements or may result in litigation;
- we may not be able to renew the existing agreement on acceptable terms;
- we may not be able to expand the Indian CAD labor force as necessary to meet market demand;
- the third party may not devote sufficient resources to the production of our CAD designs;
- the third party may fail to follow our processes, fail to provide CAD designs that meet our specifications or fail to meet regulatory or legal requirements;
- we may experience outages or other problems with our high speed network provider that may prevent or delay the third party from accessing the necessary CAD design software, which would prevent or delay the completion of the CAD designs;
- the third party may be limited or prevented from access to our high speed network provider due to U.S. or foreign government intervention or regulation; and
- the third party may be subject to labor disputes, strikes or other shutdowns, including related to severe weather.

Because we rely on a foreign entity for CAD designs for just-in-time manufacturing of our products, there are a number of risks to our business should this entity be unable to provide CAD designs within the necessary time frames or at all, including delayed or missed surgeries which could harm our reputation and our ability to sell products in the

future. We would have difficulty and incur additional cost in quickly adding CAD designers in-house or through other third parties to address any short fall in CAD design production. As a result, our ability to manufacture our products and conduct business and our financial results, including our ability to generate revenue,

would be materially impaired, market acceptance of our products could be diminished and customers may instead purchase our competitors' products.

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 manufacture 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, unexpected difficulties with manufacturing our products, or an unexpected and significant increase in the demand for our products, could lead to 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, and may also require us to seek faster, more expensive delivery methods in order to not miss surgery dates, each of 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 proprietary iFit software is critical to our business. Any delays in fixing bugs or errors and any limitations in our ability to modify such software for future products or modifications of existing products could have a material adverse impact on our business and operating results.

We rely on our iFit proprietary software applications to design and manufacture our customized implants and iJigs for each patient. These software 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 software 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.

We rely on experienced software programmers to maintain and modify our iFit software applications. Loss of such employees could materially harm our business.

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.

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.

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 sales and 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, Monaco, Hungary, Spain and Australia. 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, 2018, 2017 and 2016 approximately 13%, 17%, and 21% of our revenue was attributable to our international customers, respectively, and as of December 31, 2018, 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. and 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;
- changes in foreign medical reimbursement policies and programs;
- complex data privacy requirements and labor relations laws;
- 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;
- management communication and integration problems related to entering new markets with different languages, cultures and political systems;
- 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 in accordance with a new long range business plan, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

In the fourth quarter of 2018, we began the implementation of a new long range business plan, or the LRP, including a reduction in our total work force by approximately 10%, institution of cost reduction initiatives and a reduction of our debt facility from $30 million to $15 million. We expect to experience subsequent growth in the number of our employees and the scope of our operations following implementation of the LRP. Managing the business in accordance with the LRP will require significant attention by our management and we may be unable to successfully complete the LRP, which would require us to seek additional financing. Our management may need to adjust the LRP to increase or decrease expected growth based on our actual business performance.

If our performance allows for an increase in the growth of the number of our employees and scope of our operations, 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.

If our performance requires a further decrease in the number of our employees and scope of our operations, our management would need to spend significant attention managing this reduction and the operation of the business and such reduction could have a material adverse effect on our operating results and financial condition.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent on the managerial experience and the medical device industry expertise of principal members of our executive, scientific and development teams. We have formal employment agreements with our executive officers. These agreements do not prevent them from terminating their employment with us at any time. In addition, we do not carry key-man insurance on any of our executive officers or employees and may not carry any key-man insurance in the future.

If we lose one or more of our executive officers 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.

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 or may choose not to file in certain countries to limit expenses. 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 such that material aspects of our products and procedures may not be protected. 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 grant of a 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. For example, certain claims of certain of our issued patents were declared invalid by the U.S. Patent Office following inter parties review

proceedings brought by Smith & Nephew. See Part II, Item 3, Legal

Proceedings of this Annual Report on Form 10-K for more information on the patent proceedings brought against us by Smith & Nephew. The process of applying for patent protection itself is time consuming and expensive. The failure of our patents to protect our products and technologies adequately might make it easier for our competitors to offer the same or similar products or technologies. Competitors may be able to design around our patents or develop products that provide outcomes that are comparable to ours without infringing on our intellectual property rights.

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

If a competitor infringes or otherwise violates one of our patents, the patents of our licensors, or our other intellectual property rights, enforcing those patents, trademarks and other rights would be difficult, time consuming, expensive and 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 would 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. Moreover, bringing an infringement proceeding against a third party may result in that third party bringing claims against us that our products infringe their patents and seeking monetary damages on the sales of those products as well as injunctions against the future sales of our products.

In particular, on February 29, 2016, we filed a lawsuit against Smith & Nephew in the United States District Court for the District of Massachusetts Eastern Division. The lawsuit alleged that Smith & Nephew’s Visionaire® patient-specific instrumentation, as well as the implants systems used in conjunction with the Visionaire instrumentation, infringed eight of our patents, and requested monetary damages for willful infringement and a permanent injunction. Smith & Nephew then counter sued filing claims alleging that our products infringed ten patents owned or exclusively licensed by Smith & Nephew. This lawsuit and our settlement of it is described in more detail in Part II, Item 3, Legal Proceedings of this Annual Report on Form 10-K.

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. Though these agreements are designed to protect our proprietary information, 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. However, 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 may 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 patent rights. Certain of these license agreements impose royalty and insurance obligations on us as well as development and milestone obligations that we have met. In the future, 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. 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 increases 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;

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- 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.

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 16 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.

Product liability lawsuits have been and may continue to be brought against us which may harm our reputation, divert management’s attention, and require us to pay damages that exceed our insurance coverage, each of which may result in harm to our business.

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 and hip 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 tibia tray inserts wear and aseptic loosening, which is a condition caused by wear debris generated by the implant. Additionally, because we manufacture patient-specific instrumentation and patient-specific implants for individual patients and uniquely identify each patient’s components, we have in the past and could face future product liability claims if incorrect components are delivered for a patient. 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 have been and may continue to become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients.

We have had product liability claims relating to our products asserted against us in the past, and some product liability claims currently are outstanding. No claim to date either individually, or in the aggregate, has resulted in a material

negative impact on our business. In light of the nature of our business, it is likely we will continue to be subject to product liability claims in the future, some of which could have a negative impact on our business.
Regardless of the merit or eventual outcome, product liability claims may result in:

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

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

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

Risks related to government regulation

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

Our products are classified as medical devices and are subject to extensive regulation by the FDA and other federal, state and foreign governmental authorities. These regulations relate to manufacturing, labeling, sale, promotion, distribution, importing and exporting and shipping of our products.

If we fail to comply with applicable laws and regulations it could jeopardize our ability to sell our products and result in enforcement actions such as:

- untitled letters, warning letters, fines, injunctions or civil penalties;
- termination of distribution authorizations;
- recalls, detention and/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 place in the market or make available for sale a new regulated product or a significantly modified 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

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commercial distribution, 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 controls and labeling data.

In order to obtain a PMA approval 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, our products have only required 510(k) clearance and 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. We have been required to complete clinical studies and/or provide clinical evaluation reports in connection with obtaining regulatory approval for the sale of our products outside the United States, for example, in Australia. 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;
- sufficient patients may not enroll in clinical study 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;
- the interim or final results of the clinical trials may be inconclusive or unfavorable as to safety or effectiveness; and
- Regulatory authorities may not accept the results or validity of our clinical studies.

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 more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or 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 and a letter-to-file is written explaining the changes and retain by us. 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.

In the EU, we are required to comply with applicable medical device directives (including the Medical Devices Directive and the Active Implantable Medical Devices Directive, collectively "Directives") and obtain CE Mark certification in order to market medical devices. The CE Mark is applied following approval from an independent notified body or declaration of conformity. In the CE Marking process, a medical device manufacturer must develop a clinical plan and then carry out a clinical evaluation of its medical device to demonstrate conformity with the relevant Essential Requirements. 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 our clinical plan submitted to the Notified Body as part of our clinical evaluation process. The conduct of clinical studies is 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. 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.

After receiving a CE Certificate of Conformity 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. 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 (recertification) of the CE Certificate of Conformity. We have submitted for recertification of our iUni and iDuo products and plan to submit for recertification for our iTotal PS product through May 2024. 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.

The European Union regulatory bodies finalized a new Medical Device Regulation, or MDR, in 2017, which replaces the existing Directives and provided three years for transition and compliance. We must be compliant with the MDR by May 2020. The MDR will significantly change several aspects of the existing regulatory framework, such as clinical studies and data requirements and introduce new ones, such as unique device identification, post marketing clinical reports and patient identification. We and the Notified Bodies who will oversee compliance to the new MDR face uncertainties as the MDR is rolled out and enforced by the Commission and EEA Competent Authorities, creating risks in several areas, including the CE Marking process and data transparency, in the upcoming years. We expect to be compliant with the EU MDR on or before May 2020.

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 both the United Kingdom and the EU, 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. In either such event, the process for attaining regulatory clearance or 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 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) clearance and may even, in some circumstances, require the submission of a PMA. 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 stricter 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. On October 25, 2017, the FDA issued "Deciding When to Submit 510(k) for a Change to an Existing Device" and "Deciding When to Submit a 510K for a Software Change to an Existing Device" and "Guidances for Industry and Food and Drug Administration Staff". These guidance documents stipulate when to submit to FDA for changes to our products and attempt to clarify and provide direction for ease of decision making and supporting evidence required for changes to cleared devices. Further changes 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 a 510(k) clearance or a PMA approval by the FDA. 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 detention and/or seizure;
- consent decrees; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and most of 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, including the QSR, is subject to continual review and is monitored rigorously through periodic announced and unannounced inspections by the FDA. Following such an inspection of our Billerica, Massachusetts facility in 2018, the FDA issued to us a Form 483 with several observations, including deviations from the QSR. Following issuance of the letter, we took and continue to take various corrective

and preventative actions to help address certain of the observations and to improve our quality, production and design control systems, and we have engaged with the FDA regarding these matters. We recently

received from the FDA notification that this inspection is closed. At the request of the FDA, we plan to provide the FDA with periodic progress updates regarding these matters. Nevertheless, we cannot be certain that we will complete the various corrective and preventative measure on a schedule acceptable to the FDA, or that we will not be subject to additional inspections and/or requirements to implement additional remediation efforts.

Compliance with harmonized standards in the EU is also subject to regular review through the conduct of assessments or audits 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 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. A recall may require the removal or correction of a marketed product to repair, modify, adjust, relabel, destroy or inspect the product. 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, voluntary 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, we initiated a voluntary recall in August 2015 for approximately 950 iJigs manufactured between July 18, 2015 and August 28, 2015. We initiated this action in response to 3 complaints of moisture on the patient-specific instrumentation. We were concerned that these instruments might contain small amounts of ethylene glycol residue, a by-product of a chemical commonly used in sterilization processes. Testing at an independent laboratory determined that no ethylene glycol residue was present on the implants tested. Thus, there was no patient safety concern with the implants. The independent testing laboratory further determined that the risk of ethylene glycol induced toxicity from exposure to the patient-specific instruments was low, because, in part, ethylene glycol does not represent a practical health hazard from exposure to medical devices for exposures less than 24 hours in duration. It was determined that no additional monitoring of patients was necessary. Though there was no impact to patient safety, this voluntary recall 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 against the promotion of unapproved, or off-label, use of a device. 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 or activities constitute promotion of an unapproved, or off-label use, it could request that we modify our materials or activities 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 Bio-Compatibility Testing, 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 ACA 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 ACA. An initial version of proposed legislation designed to repeal the ACA, and replace it with a system of tax credits and dissolve an expansion of the Medicaid program was not adopted by Congress. Spending bills passed by

Congress have made some changes to the ACA. Although the previously proposed legislation intended to repeal or significantly restructure the ACA has not had sufficient support to pass Congress, there is a continued focus on and uncertainty regarding the future of the current ACA framework.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

In addition, the Centers for Medicare & Medicaid Services, or CMS, has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. And, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Changes to the ACA, 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 ACA, 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.

We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business. It is possible that repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are favorable for the research-based medical device industry could also be repealed along with ACA coverage expansion provisions. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

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 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. We may be subject to additional securities class action suits or proceedings in the future. 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.

We may have disagreements with past and present members of our scientific advisory board and our previous Chief Executive Officer and director, Dr. Lang, over the interpretation of the terms of revenue share agreements and use of resources.

We are party to revenue share agreements with certain past and present members of our scientific advisory board and our former Chief Executive Officer and former 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 interpretation of the terms of these agreements may lead to disputes with our advisors and such disputes may result in termination of the agreements, which may harm our ability to develop future products, and potentially litigation. In 2018, in connection with an accounting review, we identified overpayments made to our advisors. We have adjusted payments made in 2018 and are working with advisors to address overpayments we have made under these agreements through the provision of additional unpaid services to us by those advisors.

Beginning in June 2018, we raised concerns with Dr. Lang relating to his revenue share agreement and have been seeking to enter into discussions with Dr. Lang concerning the scope of this agreement. In October 2018, we requested that Dr. Lang provide consulting services as permitted under Dr. Lang’s revenue share agreement. However, he failed to respond to such request and, as a result, beginning in the fourth quarter of 2018, the revenue share percentage rate owed to Dr. Lang has been reduced by 50% within the scope of his agreement. Dr. Lang may agree in the future to provide consulting services under his revenue share agreement and, in such case, the revenue share percentage rate would be increased back to the original rate. In addition, we have notified Dr. Lang of overpayments we made in years prior to 2018 and the credits that we will make against future payments owed to him, including a full credit of the amount owed to him for sales made in 2018, to reimburse us for such overpayments. Dr. Lang may disagree with our interpretation of the terms of his revenue share agreement which may lead to a dispute, including potential litigation. In addition, 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.

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 clearance. 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, including the General Data Protection Regulation in the EU, 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.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. In addition, we may engage third party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management’s attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

If we are found to have violated laws protecting the privacy or security of patient health information or other personal data, we could be subject to civil or criminal penalties, litigation or regulatory investigations, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws in the United States and foreign countries protecting the privacy and security of personal data, including patient health information and patient records, and restricting the collection, use, disclosure and transfer of that protected information. In particular, Health Insurance Portability and Accountability Act, HIPAA, privacy, security and breach notification 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, limiting most use and disclosure of health information to the minimum amount reasonably necessary to accomplish the intended purpose, requiring appropriate data security measures, and requiring data breach notification in certain circumstances. Similarly, the General Data Protection Regulation, or GDPR, came into force in the European Union, or EU, on May 25, 2018 and applies to the products and services that we offer to EU patients, our reach and development activities in the EU, our online or other tracking individuals in the EU and our EU employees. The GDPR created a range of new compliance obligations, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and significantly increased financial penalties for noncompliance

(including possible fines of up to 4% of global annual revenues for the preceding financial year or €20 million (whichever is higher) for the most serious infringements). The GDPR also conferred a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities,

seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. If we or any of our service providers are found to be in violation of HIPAA rules, the GDPR, or other data protection laws, we could be subject to civil or criminal penalties, litigation, or regulatory investigations, which could increase our liabilities, harm our reputation, and have a material adverse effect on our business, financial condition, and operating results.
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
If we fail to maintain compliance with the requirements for continued listing on the Nasdaq Global Select Market, our common stock could be delisted from trading, which would adversely affect the ability to sell our stock in the public market, the liquidity of our common stock and our ability to raise additional capital.
Our common stock is currently listed for quotation on the Nasdaq Global Select Market. We are required to meet specified financial requirements in order to maintain our listing on the Nasdaq Global Select Market. On November 13, 2018, we received a deficiency letter from the Listing Qualifications Department, or the Staff, of The Nasdaq Stock Market notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Global Select Market. We were provided an initial period of 180 calendar days, or until May 12, 2019, to regain compliance with the listing requirements. As of February 28, 2019, the bid price for our common stock had closed at $1.00 or more for a minimum of 10 consecutive business days making us eligible to regain compliance with the minimum bid requirement. On March 1, 2019, we confirmed with the Listing Qualifications Analyst of Nasdaq that we had regained compliance with the listing requirements. Under certain circumstances, Nasdaq could have required that the minimum bid price exceed $1.00 for more than ten consecutive days before determining that we comply with Nasdaq's continued listing standards. If we had not regained compliance with the listing requirements, a second 180 calendar day compliance period may have been available if the Company met certain continued listing requirements, and the Company would also be required to provide notice to Nasdaq of its intent to regain compliance during the second 180 calendar day period, by effecting a reverse stock split if necessary. If in the future we fail to satisfy the Nasdaq Global Select Market's continued listing requirements, we may transfer to the OTC Bulletin Board. Any potential delisting of our common stock from the Nasdaq Global Select Market would make it more difficult for stockholders to sell our stock in the public market and would likely result in decreased liquidity, limited availability of market quotations for shares of our common stock, limited availability of news and analyst coverage regarding our Company, a decreased ability to issue additional securities and increased volatility in the price of our common stock.
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 has been and is likely to continue 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 the risk factors as described in this Annual Report on Form 10-K and:

- 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;
- 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;
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changes in FDA and foreign governmental regulatory policies, requirements and enforcement practices;

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

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

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 25.36% of our capital stock as of December 31, 2018. 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, 2018, we had federal net operating loss, or NOL, carryforwards of $404 million and state NOL carryforwards of $219 million. These federal and state NOL carryforwards will expire in future years if not utilized. Utilization of these NOL 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, on September 16, 2004, March 10, 2009, January 11, 2012 and January 29, 2018. As a result of this ownership changes, our use of NOL carryforwards generated prior to January 28, 2018 is subject to

an annual limitation of approximately $1.4 million per year. 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. Moreover, our federal NOLs from years prior to 2018 can be carried forward for a maximum of 20 years from the year in which the NOL was incurred, and our state NOLs are subject to carryforward limitations that vary from state to state; as a result, all or a portion of those carryforwards could expire before being available to reduce future income tax liabilities. Assuming no future ownership change occurs at a time when our market capitalization is lower than it was on our last ownership change on January 29, 2018, the Company is projected to lose $346 million of the total federal NOL carryforwards currently subject to IRC Section 382 to the 20-year carryforward expiration rules.

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, our current debt facility does and any future debt agreements may also preclude us from paying or place restrictions on our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain with respect to your investment for the foreseeable future.

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

We are an "emerging growth company," or EGC, as defined in the JOBS Act, and may remain an EGC until the earlier of: (1) the last day of the fiscal year in which we have total annual gross 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 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 have incurred and will continue to 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, 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 with the option to extend for two successive five year terms beyond the term of the lease. We occupy approximately 59,000 square feet of manufacturing space in Wilmington, Massachusetts under a lease that expires in July 2022 with the option to extend for one additional five-year period beyond the term of the lease. We occupy approximately 4,099 square feet of space in Wallingford, Connecticut under a five year lease that expires in August 2022 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 alleged that Smith & Nephew’s Visionaire® patient-specific instrumentation as well as the implant systems used in conjunction with the Visionaire instrumentation infringe nine of our patents, and it requested, 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 implant systems used in conjunction with the Visionaire instrumentation infringe the patents asserted by us in the lawsuit. It also alleged two affirmative defenses: that our asserted patents are invalid and that we are barred from relief under the doctrine of laches. In addition, Smith & Nephew asserted a series of counterclaims, including counterclaims seeking declaratory judgments that Smith & Nephew’s accused products do not infringe our patents and that our patents are invalid. Smith & Nephew also alleged that we infringed ten patents owned or exclusively licensed by Smith & Nephew: two of those patents Smith & Nephew alleged are infringed by our iUni and iDuo products; three of those patents Smith & Nephew alleged are infringed by our iTotal products; and five of those patents Smith & Nephew licenses from Kinamed, Inc. of Camarillo, California and alleged 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. With the dismissal of all claims involving Kinamed's patents, Kinamed was no longer a party to the lawsuit.

On January 27, 2017, Smith & Nephew filed a motion seeking a stay of the Smith & Nephew Lawsuit until any requested IPRs (defined and described below) were resolved. On April 27, 2017, the Court stayed certain aspects of the proceedings and indicated that it would make a final decision on the motion to stay after the USPTO has decided more of the petitions for Inter Partes Review ("IPR").

Between September 21, 2016 and March 1, 2017, Smith & Nephew filed sixteen petitions with the United States Patent & Trademark Office ("USPTO") requesting IPRs of the nine patents that we asserted against Smith & Nephew in the lawsuit. In its petitions, Smith & Nephew alleged that our patents were 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 ("Subject Patent Claims"). On April 24, 2018, the Supreme Court of the United States issued its ruling in SAS Institute, Inc. v. Iancu (the "SAS Decision") which held that the IPR proceedings cannot be instituted in part and denied in part. In response to the SAS Decision and guidance from the USPTO, the Patent Trial and Appeal Board ("PTAB") issued an order on April 27, 2018 including the Subject Patent Claims within the prior instituted IPR proceedings. In total, the USPTO instituted IPR proceedings for claims in six of the patents in the Smith & Nephew lawsuit (five patents that were currently asserted, and one of the patents that was voluntarily dismissed from the lawsuit), and denied the petitions for claims in three of the patents (two patents that were currently asserted and one of the patents that was voluntarily dismissed from the lawsuit). Smith & Nephew filed requests for rehearing of three of the petitions that were denied and the PTAB denied those requests. Smith & Nephew filed requests with the USPTO for reexamination of two of the patents for which IPR proceedings were not instituted and the USPTO granted those requests for reexamination. On August 7, 2018 and October 2, 2018, the USPTO ruled in our favor on both reexamination proceedings finding the claims patentable in both patents.

Between December 18, 2017 and April 18, 2018, IPR hearings were held for the six patents for which IPR proceedings were instituted. On March 26, 2018, the USPTO issued its first ruling holding that our U.S. Patent No. 9,055,953 (the "'953 Patent") is invalid over prior art. On April 19, 2018, the USPTO issued its second ruling holding that our U.S. Patent No. 9,216,025 (the "'025 Patent") is invalid over prior art. Following a grant by the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") of our request for consolidation, we filed an opening brief on October 1, 2018, appealing the PTAB's rulings on the '953 Patent and the '025 patent. On June 11, 2018, the USPTO issued its third ruling holding that a subset of claims in our U.S. Patent No. 7,981,158 (the "'158 Patent") are invalid over prior art. On June 12, 2018, the USPTO issued its fourth ruling holding that a subset of claims in our U.S. Patent No. 8,551,169 (the "'169 Patent") are invalid over prior art. The '953 Patent is not part of the lawsuit having been voluntarily dismissed on March 9, 2017. The '025, '169 and '158 Patents were part of the lawsuit. On September 26, 2018, the PTAB terminated the remaining IPR proceedings in response to a joint motion to terminate filed by us and Smith & Nephew pursuant to the Settlement and License Agreement (defined and described below).

On September 14, 2018, the Company and Smith & Nephew entered into a Settlement and License Agreement (the "Settlement and License Agreement") including terms for resolving all of the parties' existing patent disputes. The Settlement and License Agreement includes terms for dismissal of all outstanding litigation, prohibitions against commencement of litigation with respect to existing product lines, and Smith & Nephew agreed to cease their opposition to certain of our patents currently in IPR proceedings.

Pursuant to the Settlement and License Agreement, we granted to Smith & Nephew (i) a fully paid-up, non-exclusive, worldwide license to certain patents for the exploitation of patient-specific instrumentation for use with off-the-shelf knee implants, (ii) a royalty-bearing, non-exclusive, worldwide license to certain patents in the event Smith &Nephew commercializes patient-specific instrumentation for use with off-the-shelf implants other than knee implants, and (iii) a fully paid-up, non-exclusive, worldwide license to certain other patents for exploitation of off-the-shelf implants. Also pursuant to the Settlement and License Agreement, Smith & Nephew granted to us a fully paid-up, non-exclusive, worldwide license to certain patents for the exploitation of patient-specific implants and paid us $10.5 million. We are not required to make a payment to Smith & Nephew.

The foregoing description is qualified in its entirety by reference to the text of the Settlement and License Agreement filed as exhibit 10.1 to our quarterly report on Form 10-Q for the period ended September 30, 2018.

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, 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
Year ended December 31, 2018:		
First Quarter	$2.62	$1.20
Second Quarter	$1.79	$1.22
Third Quarter	$1.28	$0.89
Fourth Quarter	$1.00	$0.36

Holders of Our Common Stock

As of February 28, 2019, there were approximately 345 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.

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, 2018 and 2017 from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We have derived the balance sheet data for the years ended December 31, 2016, 2015, and 2014 respectively 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.

(in thousands, except share and per share data)	Years ended December 31, 2018	2017	2016	2015	2014
Consolidated statements of operations data:					
Revenue					
Product	$78,627	$77,100	$78,921	$62,791	$48,186
Royalty	11,162	1,015	978	4,096	—
Total revenue	89,789	78,115	79,899	66,887	48,186
Cost of revenue	41,304	49,301	53,192	45,102	32,374
Gross profit	48,485	28,814	26,707	21,785	15,812
Operating expenses:					
Sales and marketing	38,955	38,788	41,086	37,558	29,367
Research and development	16,869	17,136	16,608	16,997	15,107
General and administrative	24,622	28,737	25,157	23,191	16,763
Goodwill impairment	6,731	—	—	—	—
Total operating expenses	87,177	84,661	82,851	77,746	61,237
Loss from operations	(38,692)	(55,847)	(56,144)	(55,961)	(45,425)
Other income and expenses					
Interest income	659	491	487	138	104
Interest expense	(3,356)	(2,119)	(138)	(1,385)	(360)
Loss on extinguishment of debt	—	—	—	(205)	—
Foreign currency transaction income (loss)	(1,915)	4,057	(1,607)	—	—
Other income (expense), net	—	—	(123)	208	—
Total other income/(expenses), net	(4,612)	2,429	(1,381)	(1,244)	(256)
Loss before income taxes	(43,304)	(53,418)	(57,525)	(57,205)	(45,681)
Income tax provision	61	162	63	41	41
Net loss	$(43,365)	$(53,580)	$(57,588)	$(57,246)	$(45,722)
Net loss per share applicable to common stockholders—basic and diluted	$(0.74)	$(1.24)	$(1.39)	$(2.60)	$(10.78)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	58,886,333	43,343,459	41,521,629	21,993,066	4,239,564

(in thousands)	December 31, 2018	2017	2016	2015	2014
Consolidated balance sheet data:					
Cash and cash equivalents	$16,380	$18,348	$37,257	$117,185	$37,900
Investments	7,245	26,880	28,242	—	—
Working capital	36,581	56,942	81,577	132,894	45,036
Total assets	62,983	93,798	112,810	157,099	71,278
Long term debt, including current portion	14,792	29,667	—	478	10,620
Total stockholders' equity	36,200	46,513	94,055	141,212	49,827

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 $18.1 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 90,000 knee implants, more than 70,000 total knee implants and 20,000 partial knee implants. 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. On July 31, 2018, our first Conformis Hip Systems were implanted. We are in limited commercial launch with the Conformis Hip System and intend to enter full commercial launch in the second half of 2019.

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, Monaco, Hungary, Spain and Australia. 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 as well as health insurance coverage and reimbursement rates. 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, the timing of the introduction of our new products, if any, and the impact of the buying patterns and implant volumes of medical facilities.

On-going royalty revenue is generated from our agreement with MicroPort Orthopedics Inc., a wholly owned subsidiary of MicroPort Scientific Corporation, or collectively, MicroPort. The license agreement with MicroPort and our license agreement with Wright Medical Group, Inc., its wholly owned subsidiary, also generated additional revenue, which was recognized through December 31, 2017. Both agreements were entered into in April 2015. Historically, 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, to be recognized as royalty revenue ratably through the expiration of the last to expire of our patents and patent applications licensed to Wright Medical, which currently is expected to occur in 2027. On January 1, 2018, we adopted ASC 606, Revenue from Contracts with Customers. Our analysis of these contracts under ASC 606 indicated that the licenses are functional and thus revenue should have been recognized in full upon the license execution date, which resulted in a $4.3 million adjustment to our opening balance of accumulated deficit. In addition, the on-going royalty from MicroPort, which was previously recognized as royalty revenue upon receipt of payment, is now recognized in the period the sale occurred, resulting in a $0.2 million adjustment to our opening balance of accumulated deficit. The license agreement with MicroPort 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 2031.

Royalty revenue for the year ended December 31, 2018, includes revenue of $10.5 million generated from our settlement with Smith & Nephew for a fully paid-up, non-exclusive, worldwide license to certain patents for the exploitation of patient-specific instruments with off-the-shelf implants. Under ASC 606, the licenses are functional and thus revenue is recognized in full upon the license execution date, resulting in recognition of $10.5 million as royalty revenue.

Cost of revenue

We produce our computer-aided designs, or CAD, in-house and in India and use them to direct most 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. Starting in August 2017, we polish our femoral implants used in our total and partial knee products in our facility in Wallingford, Connecticut. Also starting in July 2018, we manufacture our patient-specific Conformis Hip System implants in our facility in Wilmington, Massachusetts. We

outsource the production of the remainder of the partial knee tibial components, femoral castings, and other knee and hip 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, outsourced CAD labor, manufacturing supplies, inbound freight, manufacturing overhead, and depreciation expense.

We calculate gross margin as revenue less cost of revenue divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, including primarily volume of units produced, mix of product

components manufactured by us versus sourced from third parties, our average selling price, the geographic mix of sales, product sales mix, the number of cancelled sales orders 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 components 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
- continue to transition our in-house CAD labor force to India, which we believe will reduce labor costs required to design our products.

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 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 of 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 expense for revenue share payments to our past and present scientific advisory board members, including one of our past 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, long-lived asset impairment charges, freight, facilities expense, and severance 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.

Goodwill impairment. Goodwill impairment expense consists of non-cash impairment charges incurred during the third-quarter ended September 30, 2018 related to the full impairment of goodwill derived from the acquisition of ImaTx, Inc. in 2009 and the acquisition of Broad Peak Manufacturing, LLC in August 2017.

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.

Consolidated results of operations

Comparison of the years ended December 31, 2018 and 2017

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

	2018		2017		2018 vs 2017	
Years Ended December 31,	Amount	As a% of Total Revenue	Amount	As a% of Total Revenue	$ Change	% Change
Revenue						
Product revenue	$78,627	88 %	$77,100	99 %	$1,527	2 %
Royalty	11,162	12	1,015	1	10,147	1,000
Total revenue	89,789	100	78,115	100	11,674	15
Cost of revenue	41,304	46	49,301	63	(7,997)	(16)
Gross profit	48,485	54	28,814	37	19,671	68
Operating expenses:						
Sales and marketing	38,955	43	38,788	50	167	—
Research and development	16,869	19	17,136	22	(267)	(2)
General and administrative	24,622	27	28,737	37	(4,115)	(14)
Goodwill impairment	6,731	7	—	—	6,731	100
Total operating expenses	87,177	97	84,661	108	2,516	3
Loss from operations	(38,692)	(43)	(55,847)	(71)	17,155	31
Total other income/(expenses), net	(4,612)	(5)	2,429	3	(7,041)	(290)
Loss before income taxes	(43,304)	(48)	(53,418)	(68)	10,114	19
Income tax provision	61	—	162	—	(101)	(62)
Net loss	$(43,365)	(48)%	$(53,580)	(69)%	$10,215	19 %

Product revenue. Product revenue was $78.6 million for the year ended December 31, 2018 compared to $77.1 million for the year ended December 31, 2017, an increase of $1.5 million or 2%, due principally to increased sales of our iTotal PS and Hip, partially offset by decreased sales of our iTotal CR and partial knee products.

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):

	2018		2017		2018 vs 2017	
Years Ended December 31,	Amount	As a % of Product Revenue	Amount	As a % of Product Revenue	$ Change	% Change
United States	$68,057	87 %	$64,307	83 %	$3,750	6 %
Germany	9,007	11	11,296	15	(2,289)	(20)
Rest of world	1,563	2	1,497	2	66	4
Product revenue	$78,627	100 %	$77,100	100 %	$1,527	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 87% for the year ended

December 31, 2018 compared to 83% for the year ended December 31, 2017. We believe the higher level of revenue as a percentage of product revenue inside the United States in 2018 was due to the growth of the iTotal PS and Hip in the United States, coupled with the continued weakness primarily due to reimbursement challenges in our iTotal CR and partial knee product in Germany .

Royalty revenue. Royalty revenue was $11.2 million for the year ended December 31, 2018 compared to $1.0 million for the year ended December 31, 2017, an increase of $10.1 million or 999.7%. The increase was driven by the $10.5 million royalty payment under the Settlement and License Agreement with Smith and Nephew partially offset by lower ongoing royalty revenue from MicroPort Orthopedics Inc. of $0.4 million.

Cost of revenue, gross profit and gross margin. Cost of revenue was $41.3 million for the year ended December 31, 2018 compared to $49.3 million for the year ended December 31, 2017, a decrease of $8.0 million or 16%. The decrease was due primarily to cost reductions from our vertical integration efforts and other cost saving initiatives. Gross profit was $48.5 million for the year ended December 31, 2018 compared to $28.8 million for the year ended December 31, 2017, an increase of $19.7 million or 68%. Gross margin was 54% for the year ended December 31, 2018 compared to 37% for the year ended December 31, 2017, an increase of 1,700 basis points. The increase in gross margin was driven primarily by cost reductions as a result of vertical integration efforts and other cost saving initiatives and the $10.5 million royalty received under the Settlement and License Agreement with Smith & Nephew, which contributed 600 basis points of the increase.

Sales and marketing. Sales and marketing expense was $39.0 million for the year ended December 31, 2018 compared to $38.8 million for the year ended December 31, 2017, an increase of $0.2 million or 0%. The increase was due primarily to an increase of $0.3 million marketing and promotional expenses, an increase in depreciation expense of $0.2 million driven by capitalization of reusable instrument trays, and a $1.0 million increase in commissions partially offset by a decrease in salaries and benefits of $1.0 million due to employee conversion to distributor agents and decrease in other sales and marketing expenses of $0.3 million.

Research and development. Research and development expense was $16.9 million for the year ended December 31, 2018 compared to $17.1 million for the year ended December 31, 2017, a decrease of $0.3 million or 2%. The decrease was due to a decrease of $1.0 million in salaries and benefits and a $0.5 million decrease in revenue share expense, partially offset by an increase of $0.9 million in prototype and validation testing expense for the hip system limited launch and other development projects, and an increase of $0.3 million in other research and development expenses.

General and administrative. General and administrative expense was $24.6 million for the year ended December 31, 2018 compared to $28.7 million for the year ended December 31, 2017, a decrease of $4.1 million or 14%. The decrease is primarily due to decreases of $3.4 million in litigation and other legal costs, $2.0 million in salaries and benefits, $0.7 million in business insurance, and $0.6 million in facility related expenses. The decrease was partially offset by increases in long-lived asset impairment of $1.3 million, a $0.6 million refund in 2017 of previously paid medical device excise tax, $0.5 million in consulting services expense, and $0.2 million in other expenses.

Goodwill impairment. Goodwill impairment was $6.7 million for the year ended December 31, 2018 compared to no impairment for the year ended December 31, 2017. The decrease in our market capitalization prior to filing the Form 10-Q for the period ended September 30, 2018 and cash flow position were indicators of impairment and our analysis determined goodwill was fully impaired.

Total other income (expenses), net. Total other income (expenses), net was a net expense of $4.6 million for the year ended December 31, 2018 compared to a net income of $2.4 million for the year ended December 31, 2017, a change of $7.0 million, or 290%. The change was primarily due to $1.9 million in foreign exchange transaction loss in 2018 compared to $4.1 million foreign exchange transaction gain in 2017, which was attributable to the effect of exchange rate change on intercompany debt with our foreign subsidiaries, and an increase of $1.2 million in interest expense associated with our term debt partially offset by an increase in interest income from investments of $0.2 million.

Income taxes. Income tax provision was $61,000 for the year ended December 31, 2018 and $162,000 for the year ended December 31, 2017. 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, H.R. 1 (“the 2017 Act”) became law. The 2017 Act includes a broad range of topics affecting corporations – including corporate tax rates, business deductions and international provisions. The effect of the tax law changes has been recognized in the Company's December 31, 2018 financial statements.

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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):

Years Ended December 31,	2017 Amount	2017 As a% of Total Revenue	2016 Amount	2016 As a% of Total Revenue	2017 vs 2016 $ Change	2017 vs 2016 % 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. 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 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):

Years Ended December 31,	2017 Amount	2017 As a % of Product Revenue	2016 Amount	2016 As a % of Product Revenue	2017 vs 2016 $ Change	2017 vs 2016 % Change
United States	$64,307	83 %	$62,366	79 %	$1,941	3 %
Germany	11,296	15	14,701	19	(3,405)	(23)
Rest of world	1,497	2	1,854	2	(357)	(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 of the United States was generated through our direct sales force and distributors. The percentage of product revenue generated in the United States was 83% 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 a net income of $2.4 million for the year ended December 31, 2017 compared to a net expense of $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 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 maintained a full valuation allowance for deferred tax assets.

On December 22, 2017, H.R.1., known as the Tax Cuts and Jobs 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.

Liquidity, capital resources and plan of operations

Sources of liquidity and funding requirements

Since our inception in June 2004, we have financed its operations primarily through private placements of preferred stock, its initial public offering in July 2015 and secondary public offering in January 2018, patent licenses, debt and convertible debt financings, equipment purchase loans, and product revenue beginning in 2007. We have not yet attained profitability and continue to incur operating losses and negative operating cash flows, which adversely impacts our ability to continue as a going concern. At December 31, 2018, we had an accumulated deficit of $475.7 million.

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

On January 6, 2017, we entered into the 2017 Secured Loan Agreement with Oxford. 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. On December 13, 2018, we pre-paid $15 million principal amount of the $30 million outstanding principal amount using short-term investment maturities and cash and cash equivalents. New minimum revenue milestones, based on product revenue projections, are to be established prior to the start of 2020 and prior to the start of each fiscal year thereafter by the mutual agreement of Oxford and the Company. If the Company is not able to agree with Oxford on new minimum revenue milestones for 2020 or a fiscal year thereafter, the Company must refinance the 2017 Secured Loan Agreement by March 31, 2020 or that next fiscal year, and if the Company fails to refinance the 2017 Secured Loan Agreement, the Company must notify Oxford of such default and Oxford would be permitted to exercise remedies against us and its assets in respect of such event of default, including taking control of our cash and commencing foreclosure proceedings on our other assets. 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.

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 U.S. Securities Act of 1933, as amended. We are not obligated to sell any shares of our common stock under the Distribution Agreement. As of December 31, 2018, we sold 785,280 Shares under the Distribution Agreement resulting in net proceeds of $1.5 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.

In addition, the Smith & Nephew settlement and license agreement, discussed in Note J-Commitments and Contingencies, Legal proceedings, provided the Company with $10.5 million of royalty revenue for the year ended

December 31, 2018.

On December 17, 2018, we entered into a stock purchase agreement with Lincoln Park Capital ("LPC" and the "LPC Agreements"). Upon entering into the LPC Agreements, we sold 1,921,968 shares of common stock for $1.0 million to LPC, representing a premium of 110% to the previous day's closing price. As consideration for LPC’s commitment to purchase shares of common stock under the LPC Agreements, we issued 354,430 shares to LPC. We have the right at our sole discretion to sell to LPC up to $20.0 million worth of shares over a 36-month period subject to the terms of the LPC Agreements. We will control the timing of any sales to LPC and LPC will be obligated to make purchases of our common stock upon receipt of requests from us in accordance with the terms of

the LPC Agreements. There are no upper limits to the price per share LPC may pay to purchase the up to $20.0 million worth of common stock subject to the LPC Agreements, and the purchase price of the shares will be based on the then prevailing market prices of our shares at the time of each sale to LPC as described in the LPC Agreements, provided that LPC will not be obligated to make purchases of our common stock pursuant to receipt of a request from us on any business day on which the last closing trade price of our common stock on the Nasdaq Capital Market (or alternative national exchange in accordance with the LPC Agreements) is below a floor price of $0.25 per share. No warrants, derivatives, financial or business covenants are associated with the LPC Agreements and LPC has agreed not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of shares of our common stock. The LPC Agreements may be terminated by us at any time, at our sole discretion, without any cost or penalty.

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

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

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

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

At December 31, 2018, we had cash and cash equivalents and investments of $23.6 million and $0.5 million in restricted cash allocated to lease deposits. Based on our current operating plan, we expect that our existing cash and cash equivalents and investments as of December 31, 2018, anticipated revenue from operations, and the ability to issue equity to LPC will enable us to fund our operating expenses and capital expenditure requirements and pay our debt service as it becomes due for at least the next 12 months from the date of filing. We have based this expectation on assumptions that may prove to be wrong, such as the revenue that we expect to generate from the sale of our products, the gross profit we expect to generate from those revenue, the reduction in operating expenses beginning in

2019, and we could use our capital resources sooner than we expect.

Cash flows

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

	Years Ended December 31,			
	2018	2017	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$(26,982)	$(37,856)	$10,874	29 %
Investing activities	15,626	(10,041)	25,667	256
Financing activities	7,655	32,697	(25,042)	(77)
Effect of exchange rate on cash	1,733	(3,709)	5,442	147
Total	$(1,968)	$(18,909)	$16,941	90 %

Net cash used in operating activities. Net cash used in operating activities was $27.0 million for the year ended December 31, 2018 and $37.9 million for the year ended December 31, 2017, a decrease of $10.9 million. These amounts primarily reflect net losses of $43.4 million for the year ended December 31, 2018 and $53.6 million for the year ended December 31, 2017. Non-cash reconciling items between Net loss and cash used in operations for the year ended December 31, 2018 includes a decrease in goodwill impairment of $6.7 million and $1.5 million in other non-cash items partially offset by an increase in stock-based compensation expense of $2.2 million. The remaining change is related to our operating assets and liabilities, including an increase from prepaid and other assets of $1.2 million, an increase from inventory of $2.9 million, an increase from accounts receivable of $1.5 million and an increase from other long-term liabilities of $0.5 million, offset by a decrease of $0.4 million from accounts payable and accrued liabilities.

Net cash provided by (used in) investing activities. Net cash provided by investing activities was $15.6 million for the year ended December 31, 2018 compared to $10.0 million cash used in investing activities for the year ended December 31, 2017, an increase of $25.7 million. These amounts primarily reflect an increase of $18.6 million from the purchase and maturity of investment securities classified as available-for-sale, an increase of $1.2 million from cash used for purchases of property and equipment, an increase of $5.8 million from our acquisition of BPM, and an increase of $0.2 million from restricted cash balance.

Net cash provided by financing activities. Net cash provided by financing activities was $7.7 million for the year ended December 31, 2018 and $32.7 million for the year ended December 31, 2017, a decrease of $25.0 million. The decrease was due to a decrease of $30.0 million from proceeds from the issuance of debt, a decrease of $15.0 million from payments on notes payable, and a decrease of $2.0 million from proceeds from exercise of common stock options, partially offset by an increase of $21.7 million net proceeds from the issuance of common stock.

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

	Years Ended December 31,			
	2017	2016	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$(37,856)	$(49,132)	$11,276	23 %
Investing activities	(10,041)	(35,425)	25,384	72
Financing activities	32,697	3,602	29,095	808
Effect of exchange rate on cash	(3,709)	1,027	(4,736)	(461)
Total	$(18,909)	$(79,928)	$61,019	76 %

Net cash used in operating activities. Net cash used in operating activities was $37.9 million for the year ended December 31, 2017 and $49.1 million for the year ended December 31, 2016, a decrease of $11.3 million. These amounts primarily reflect net losses of $53.6 million for the year ended December 31, 2017 and $57.6 million for the year ended December 31, 2016. The net cash used in operating activities for the year ended December 31, 2017 was primarily affected by changes in our operating assets and liabilities, including a decrease from prepaid and other assets of $3.3 million, a decrease from inventory of $2.7 million, a decrease from accounts receivable of $1.5 million and a decrease from other long-term liabilities of $0.5 million, as well as a decrease from

non-cash expenses totaling $2.0 million, offset by an increase of $2.8 million from accounts payable and accrued liabilities.

Net cash used in investing activities. Net cash used in investing activities was $10.0 million for the year ended December 31, 2017 and $35.4 million for the year ended December 31, 2016, a decrease of $25.4 million. These amounts primarily reflect a decrease of $34.6 million from the purchase of investment securities classified as available-for-sale, a decrease of $1.9 million from cash used for purchases of property and equipment, offset by an increase of $4.9 million from maturity of investments, an increase of $5.8 million from our acquisition of BPM, and an increase of $0.5 million from restricted cash balance. We anticipate that the amount of cash used in investing activities will decrease in 2018 as we have purchased most of the property and equipment to manufacture the planned components in our own facility.

Net cash provided by financing activities. Net cash provided by financing activities was $32.7 million for the year ended December 31, 2017 and $3.6 million for the year ended December 31, 2016, an increase of $29.1 million. The increase was due to an increase of $30.0 million from proceeds from the issuance of debt, an increase of $1.0 million net proceeds from the issuance of common stock and an increase of $0.5 million from payments on notes payable, offset by a decrease of $2.0 million from proceeds from exercise of common stock options.

Contractual obligations and commitments

The following table summarizes our contractual obligations as of the year ended December 31, 2018 (in thousands):

	Payment Due by Period				
Contractual Obligations	Total	Less than 1 year	Years 1 to 3	Years 3 to 5	After 5 years
Senior secured debt (1)	$15,000	$—	$14,375	$625	$—
Operating lease obligations - real estate (2)	9,122	1,558	3,228	2,450	1,886
Other (3)	1,355	526	650	179	—
Total (4)	$25,477	$2,084	$18,253	$3,254	$1,886

(1) Represents amounts payable under the 2017 Secured Loan Agreement with Oxford.
(2) Represents operating lease commitments for office and manufacturing space in Wilmington and Billerica, Massachusetts, and Wallingford, Connecticut.
(3) Represents amounts payable under our product royalty agreement, operating leases for office equipment, automobile leases, and a software development collaboration project with a remaining term in excess of one year.
(4) This table does not include: (a) revenue share obligations to past and present members of our scientific advisory board and one of our past directors, as the amounts of such payments are not known with certainty; and (b) contracts that are entered into in the ordinary course of business that are not material in the aggregate in any period presented above. See "—Revenue share agreements" for a description of our revenue share arrangements.

Revenue share agreements

We are party to revenue share agreements with certain past and present members of our scientific advisory boards under which these advisors agreed to participate on our scientific advisory board and to assist with the development of our customized implant products and related intellectual property. These agreements provide that we will pay the advisor a specified percentage of our net revenue, ranging from 0.1% to 1.33%, with respect to our products on which the advisor made a technical contribution or, in some cases, which are covered by a claim of one of our patents on which the advisor is a named inventor. The specific percentage is determined by reference to product classifications set forth in the agreement and may be tiered based on the level of net revenue collected by us on such product sales.

Our payment obligations under these agreements typically expire a fixed number of years after expiration or termination of the agreement, but in some cases expire on a product-by-product basis or expiration of the last to expire of our patents for which the advisor is a named inventor that has claims covering the applicable product.

Philipp Lang, M.D., our former Chief Executive Officer and former director, joined our scientific advisory board in 2004 prior to becoming an employee. We entered into a revenue share agreement with Dr. Lang in 2008 when he became our Chief Executive Officer. In 2011, we entered into an amended and restated revenue share agreement with Dr. Lang. Under this agreement, the specified percentage of our net revenue payable to Dr. Lang ranges from 0.875% to 1.33% and applies to all of our current products, including our iUni, iDuo, iTotal Cr, iTotal PS products, and Conformis Hip System products, as well as certain other knee, hip and shoulder replacement products and related instrumentation we may develop in the future. Our payment obligations under this agreement expire on a product-by-product basis on the last to expire of our patents on which Dr. Lang is named as an inventor that has a claim covering the applicable product. These payment obligations survived termination of Dr. Lang's employment with us. We have raised concerns with Dr. Lang relating to this revenue share agreement and have been seeking to enter into discussion with Dr. Lang concerning the scope of this agreement. In October of 2018, we requested that Dr. Lang provide consulting services as permitted under Dr. Lang's revenue share agreement. However, he failed to respond to such request and, as a result, beginning in the fourth quarter of 2018, the revenue share percentage rate owed to Dr. Lang has been reduced by 50% within the scope of his agreement. We incurred revenue share expense for Dr. Lang of $0.7 million, $1.0 million, and $1.0 million for the years ended December 31, 2018, 2017 and 2016, respectively.

The aggregate revenue share percentage of net revenue from our currently marketed knee replacement products, including percentages under revenue share agreements with all of our scientific advisory board members and Dr. Lang, ranges, depending on the particular product, from 3.4% to 5.19%. We incurred aggregate revenue share expense, included in research and development, including all amounts payable under our scientific advisory board and Dr. Lang revenue share agreements of $3.1 million during the year ended December 31, 2018, representing 4.0% of product revenue, $3.7 million during the year ended December 31, 2017, representing 4.8% of product revenue, and $3.5 million during the year ended December 31, 2016, representing 4.4% of product revenue. For further information, see “Note J—Commitments and Contingencies —Revenue Share Agreements” or “Note L—Related Party Transactions —Revenue Share Agreement” in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

Segment information

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

Off-balance sheet arrangements

Through December 31, 2018, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical accounting policies and significant judgments and use of estimates

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

described in "Note B-Summary of Significant Accounting Policies" to the consolidated financial statements appearing in this Annual Report on Form 10-K.

Revenue recognition

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, Monaco, Hungary, Spain and Australia. 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, the timing of the introduction of our new products, if any, and the impact of the buying patterns and implant volumes of medical facilities.

Product revenue is recognized when, or as, obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer (“transaction price”). When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company’s contracts contained a significant financing component as of December 31, 2018. Payment is typically due between 30 - 60 days from invoice.

To the extent that the transaction price includes variable consideration, such as prompt-pay discounts or rebates, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value to which the Company expects to be entitled. Variable consideration is included in the transaction price if, in the Company’s judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Actual amounts of consideration ultimately received may differ from the Company's estimates. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company’s anticipated performance and all information (historical, current and forecasted) that is reasonably available.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on observable prices or a cost-plus margin approach when one is not available. Revenue is recognized at the time the related performance obligation is satisfied by transferring control of a promised good or service to a customer. The Company's performance obligations are satisfied at the same time, typically upon surgery, therefore, product revenue is recognized at a point in time upon completion of the surgery. Since the Company does not have contracts that extend beyond a duration of one year, there is no transaction price related to performance obligations that have not been satisfied.

Certain customer contracts include terms that allow the Company to bill for orders that are cancelled after the product is manufactured and could result in revenue recognition over time. However, the impact of applying over time revenue

recognition was deemed immaterial.

On-going royalty revenue is generated from our agreement with MicroPort Orthopedics Inc., a wholly owned subsidiary of MicroPort Scientific Corporation, or collectively, MicroPort. The license agreement with MicroPort and our license agreement with Wright Medical Group, Inc. and its wholly owned subsidiary Wright Medical Technology, Inc. also generated additional revenue, which was recognized through December 31, 2017. Both agreements entered into in April 2015. On January 1, 2018, we adopted ASC 606, Revenue from Contracts with Customers. Our analysis of these contracts under ASC 606 indicated that the licenses are functional and thus revenue should have been recognized in full upon the license execution date, which resulted in a $4.3 million adjustment to our opening balance of accumulated deficit. In addition, the on-going royalty from MicroPort, which was previously recognized as royalty revenue upon receipt of payment, is now recognized in the period the sale occurred, resulting in a $0.2 million adjustment to our opening balance of accumulated deficit.

Accounts receivable and allowance for doubtful accounts

Accounts receivable consist of billed and unbilled amounts due from medical facilities. Upon completion of a procedure, we recognize revenue and an unbilled receivable is recorded. Upon receipt of a purchase order number from a medical facility, we record a billed receivable and reverse the unbilled receivable. As a result, the unbilled receivable balance fluctuates based on the timing of our receipt of purchase order numbers from the medical facilities. In estimating whether accounts receivable can be collected, we perform evaluations of customers and continuously monitor collections and payments and estimate an allowance for doubtful accounts based on the aging of the underlying invoices, collections experience to date and any specific collection issues that have been identified. The allowance for doubtful accounts is recorded in the period in which revenue is recorded or at the time potential collection risk is identified.

Inventories

Inventories consist of raw materials, work-in-process components and finished goods. Inventories are stated at the lower of cost, determined using the first-in first-out method, or market value. We regularly review our inventory quantities on hand and related cost and record a provision for any excess or obsolete inventory based on its estimated forecast of product demand and existing product configurations. We also review our inventory value to determine if it reflects the lower of cost or market, with market determined based on net realizable value. Appropriate consideration is given to inventory items sold at negative gross margin, purchase commitments and other factors in evaluating net realizable value. During the years ended December 31, 2018, 2017 and 2016, we recognized provisions of $1.9 million, $2.6 million and $3.5 million, respectively, to adjust our inventory value to the lower of cost or net realizable value for estimated unused product related to known and potential cancelled cases, which is included in cost of revenue.

Business combinations and purchase accounting

We record our results of operations from our business acquisitions as of the applicable acquisition date. The purchase price of the acquisition is allocated to the assets acquired and liabilities assumed based on their estimated fair values. The excess of the purchase price over the fair values of these identifiable assets and liabilities is recorded as goodwill. Acquisition-related expenses are recognized separately from the business combination and are expensed as incurred.

Goodwill

Goodwill relates to amounts that arose in connection with the acquisition of ImaTx, Inc. in 2009 and the acquisition of BPM in August 2017. We test goodwill at least annually for impairment, or more frequently when events or changes in circumstances indicate that the assets may be impaired. This impairment test is performed annually during the fourth quarter at the reporting unit level. Goodwill may be considered impaired if the carrying value of the reporting unit, including goodwill, exceeds the reporting unit’s fair value. We are comprised of one reporting unit. When testing goodwill for impairment, we first assess the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. This qualitative analysis is used as a basis for determining whether it is necessary to perform the one-step goodwill impairment analysis. If we determine that it is more likely than not that its fair value is less than its carrying amount, then the one-step goodwill impairment test will be performed. During the three months ended September 30, 2018, the Company's qualitative analysis indicated a triggering event required a step one analysis to determine the fair value of the reporting unit for the period ended September 30, 2018. Our drop in market capitalization and decrease in cash flow position were indicators of impairment. We have one reporting unit and therefore the analysis is based on the Company as a whole. We determined the fair value of our Company using the combination of its market capitalization, income approach, and the merger and acquisition method concluding that the fair value of the Company is less than the carrying amount in excess of Goodwill, therefore fully impairing Goodwill. During the year ended December 31, 2017, there were no

triggering events which required a goodwill impairment assessment.

Intangibles and other long-lived assets

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

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

Furthermore, periodically we assess whether long-lived assets, including intangible assets, should be tested for recoverability whenever events or circumstances indicate that their carrying value may not be recoverable. To evaluate for impairment, we compare the undiscounted cash flows to be generated from such assets or groups of assets to the carrying value. If the undiscounted cash flows are less than the carrying value, the amount of impairment is measured based on fair value. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, we may be required to record impairment charges. In 2018, we recognized $2.4 million in impairment charges, comprised of $1.9 million related to unused manufacturing equipment abandoned in July 2018, $0.3 million related to the expiration of a credit towards a purchase of certain manufacturing equipment, and the remaining $0.2 million impairment charges related primarily to the discontinuance of software applications. In 2017, we recognized $1.1 million in impairment charges of which $0.8 million related to the discontinuance of a software capital project and $0.3 million related to intellectual property rights licensed as part of the ImaTx spin-out transaction in 2004. In 2016, a $0.1 million impairment charge was recognized in connection with certain manufacturing equipment previously purchased that will be returned to the seller in exchange for credit toward a future purchase, which value is less than the book value of the equipment. Impairment charges are included in General and administrative expense.

Stock-based compensation

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

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

JOBS Act accounting election

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

Recent accounting pronouncements

See “Note B —Summary of Significant Accounting Policies” to the financial statements in this Annual Report on Form 10-K for a full description of recent accounting pronouncements, including the expected dates of adoption and estimated effects on results of operations and financial condition.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Conformis, Inc.

Opinion on the financial statements
We have audited the accompanying consolidated balance sheets of Conformis, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.
Basis for opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.
Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP
We have served as the Company's auditor since 2008.

Boston, Massachusetts
March 12, 2019

CONFORMIS, INC. AND SUBSIDIARIES

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

	December 31, 2018	December 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	$ 16,380	$ 18,348
Investments	7,245	26,880
Accounts receivable, net	13,244	13,200
Royalty receivable	145	—
Inventories	9,534	9,184
Prepaid expenses and other current assets	1,408	2,246
Total current assets	47,956	69,858
Property and equipment, net	14,439	16,514
Other Assets		
Restricted cash	462	462
Intangible assets, net	109	210
Goodwill	—	6,731
Other long-term assets	17	23
Total assets	$ 62,983	$ 93,798
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,445	$ 4,891
Accrued expenses	7,930	7,720
Deferred revenue	—	305
Total current liabilities	11,375	12,916
Other long-term liabilities	616	651
Deferred tax liabilities	—	37
Deferred revenue	—	4,014
Long-term debt, less debt issuance costs	14,792	29,667
Total liabilities	26,783	47,285
Commitments and contingencies	—	—
Stockholders’ equity		
Preferred stock, $0.00001 par value: Authorized: 5,000,000 shares authorized at December 31, 2018 and December 31, 2017; no shares issued and outstanding as of December 31, 2018 and December 31, 2017	—	—
Common stock, $0.00001 par value: Authorized: 200,000,000 shares authorized at December 31, 2018 and December 31, 2017; 65,290,879 and 45,528,519 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	1	—
Additional paid-in capital	513,336	486,570
Accumulated deficit	(475,667)	(436,821)
Accumulated other comprehensive loss	(1,470)	(3,236)
Total stockholders’ equity	36,200	46,513
Total liabilities and stockholders’ equity	$ 62,983	$ 93,798

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

CONFORMIS, INC. AND SUBSIDIARIES

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

	Years Ended December 31,		
	2018	2017	2016
Revenue			
Product	$78,627	$77,100	$78,921
Royalty	11,162	1,015	978
Total revenue	89,789	78,115	79,899
Cost of revenue	41,304	49,301	53,192
Gross profit	48,485	28,814	26,707
Operating expenses			
Sales and marketing	38,955	38,788	41,086
Research and development	16,869	17,136	16,608
General and administrative	24,622	28,737	25,157
Goodwill impairment	6,731	—	—
Total operating expenses	87,177	84,661	82,851
Loss from operations	(38,692)	(55,847)	(56,144)
Other income and expenses			
Interest income	659	491	487
Interest expense	(3,356)	(2,119)	(138)
Foreign currency transaction income (loss)	(1,915)	4,057	(1,607)
Other income (expense)	—	—	(123)
Total other income (expenses), net	(4,612)	2,429	(1,381)
Loss before income taxes	(43,304)	(53,418)	(57,525)
Income tax provision	61	162	63
Net loss	$(43,365)	$(53,580)	$(57,588)
Net loss per share - basic and diluted	$(0.74)	$(1.24)	$(1.39)
Weighted average common shares outstanding - basic and diluted	58,886,333	43,343,459	41,521,629

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

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss
(in thousands)

	Years Ended December 31,		
	2018	2017	2016
Net loss	$(43,365)	$(53,580)	$(57,588)
Other comprehensive income (loss)			
Foreign currency translation adjustments	1,733	(3,709)	1,027
Change in unrealized gain (loss) on available-for-sale securities, net of tax	33	(26)	(7)
Comprehensive loss	$(41,599)	$(57,315)	$(56,568)

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Par Value				
Balance, December 31, 2015	41,110,127	—	467,075	(325,342)	(521)	141,212
Issuance of common stock—option exercise	1,467,692	—	4,087			4,087
Issuance of common stock—restricted stock	804,019	—	—			—
Issuance of common stock —warrant exercise	17,709	—	—			—
Compensation expense related to issued stock options and restricted stock awards			5,324			5,324
Net loss				(57,588)		(57,588)
Other comprehensive income					1,020	1,020
Balance, December 31, 2016	43,399,547	$ —	$476,486	$(382,930)	$ 499	$94,055
Issuance of common stock—option exercise	535,734	—	2,108			2,108
Issuance of common stock—restricted stock	1,195,196	—	—			—
Issuance of common stock—ATM offering	228,946	—	1,023			1,023
Issuance of common stock— Broad Peak Manufacturing, LLC acquisition	169,096	—	594			594
Compensation expense related to issued stock options and restricted stock awards			6,048			6,048
Cumulative-effect adjustment from adoption of ASU 2016-09			311	(311)		—
Net loss				(53,580)		(53,580)
Other comprehensive income					(3,735)	(3,735)
Balance, December 31, 2017	45,528,519	$ —	$486,570	$(436,821)	$ (3,236)	$46,513
Issuance of common stock—option exercise	80,000	—	112			112
Issuance of common stock—restricted stock	1,516,295	—	—			—
Issuance of common stock—2018 offering	15,333,333	1	21,324			21,325
Issuance of common stock— ATM offering	556,334	—	456			456
Issuance of common stock - Lincoln Park Capital Fund, LLC	2,276,398	—	988			988
Compensation expense related to issued stock options and restricted stock awards			3,886			3,886
Cumulative-effect adjustment from adoption of ASC 606				4,519		4,519
Net loss				(43,365)		(43,365)
Other comprehensive income					1,766	1,766
Balance, December 31, 2018	65,290,879	$ 1	$513,336	$(475,667)	$ (1,470)	$36,200

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

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2018	2017	2016
Cash flows from operating activities			
Net loss	$(43,365)	$(53,580)	$(57,588)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation and amortization expense	4,122	3,669	3,153
Amortization of debt discount	—	—	7
Stock-based compensation expense	3,886	6,048	5,324
Provision for bad debts on trade receivables	(72)	(15)	188
Impairment of goodwill	6,731	—	—
Impairment of long term assets	2,433	1,113	123
Disposal of long term assets	(4)	—	16
Non-cash interest expense	125	100	—
Amortization/accretion on investments	(18)	202	315
Deferred tax	(37)	37	—
Changes in operating assets and liabilities:			
Accounts receivable	28	1,490	4
Royalty receivable	55	—	—
Inventories	(350)	2,535	(200)
Prepaid expenses and other assets	529	1,770	(1,550)
Accounts payable and accrued liabilities	(1,011)	(1,406)	1,437
Deferred royalty revenue	—	(306)	(305)
Other long-term liabilities	(34)	487	(56)
Net cash used in operating activities	(26,982)	(37,856)	(49,132)
Cash flows from investing activities:			
Acquisition of property and equipment	(4,059)	(5,233)	(7,161)
Business acquisition, net of cash acquired	—	(5,780)	—
(Increase) decrease in restricted cash	—	(162)	300
Purchase of investments	(27,430)	(30,991)	(65,614)
Maturity of investments	47,115	32,125	37,050
Net cash provided/(used) in investing activities	15,626	(10,041)	(35,425)
Cash flows from financing activities:			
Proceeds from exercise of common stock options	112	2,108	4,087
Debt issuance costs	—	(434)	—
Proceeds from issuance of debt	—	30,000	—
Payments on long-term debt	(15,000)	—	(485)
Debt prepayment fee	(225)	—	—
Net proceeds from issuance of common stock	22,768	1,023	—
Net cash provided by financing activities	7,655	32,697	3,602
Foreign exchange effect on cash and cash equivalents	1,733	(3,709)	1,027
Decrease in cash and cash equivalents	(1,968)	(18,909)	(79,928)

Cash and cash equivalents, beginning of period	18,348	37,257	117,185
Cash and cash equivalents, end of period	$16,380	$18,348	$37,257
Supplemental information:			
Cash paid for interest	2,837	1,449	48
Non cash investing and financing activities			
Issuance of common stock for business acquisition	—	594	—
Issuance of common stock for equity financing	77	—	—

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

CONFORMIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note A—Organization and Basis of Presentation

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

The Company was incorporated in Delaware and commenced operations in 2004. The Company introduced its iUni and iDuo in 2007, its iTotal CR in 2011, its iTotal PS in 2015, and its Conformis Hip System in 2018 through a limited commercial launch. The Company has its corporate offices in Billerica, Massachusetts.

These consolidated financial statements and related notes have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

Liquidity and operations

Since the Company's inception in June 2004, it has financed its operations primarily through private placements of preferred stock, its initial public offering in July 2015 and secondary public offering in January 2018, patent licenses, debt and convertible debt financings, equipment purchase loans, and product revenue beginning in 2007. The Company has not yet attained profitability and continues to incur operating losses and negative operating cash flows, which adversely impacts the Company's ability to continue as a going concern. At December 31, 2018, the Company had an accumulated deficit of $475.7 million.

At December 31, 2018, the Company had cash and cash equivalents and investments of $23.6 million and $0.5 million in restricted cash allocated to a lease deposit.

On January 6, 2017, the Company entered into the 2017 Secured Loan Agreement with Oxford, and accessed $15 million of borrowings under Term Loan A at closing and an additional $15 million of borrowings under Term Loan B on June 30, 2017. The Company was unable to access an additional $20 million potentially available to borrow through June 2018 due to a failure to satisfy certain revenue milestones and customary drawdown conditions. Pursuant to a fifth amendment to the 2017 Secured Loan Agreement, or the Fifth Amendment, on December 13, 2018, the Company pre-paid $15 million aggregate principal amount of the $30 million outstanding principal amount, as a pro rata portion of the Term A Loan and Term B Loan, together with accrued and unpaid interest thereon and a pro rata prepayment fee. The Company used short-term investment maturities and cash and cash equivalents to fund this prepayment.
The Fifth Amendment also reduced the revenue milestones through December 31, 2019. New minimum revenue milestones, based on product revenue projections, are to be established prior to the start of 2020 and prior to the start of each fiscal year thereafter by the mutual agreement of Oxford and the Company. If the Company is not able to agree with Oxford on new minimum revenue milestones for 2020 or a fiscal year thereafter, the Company must refinance the 2017 Secured Loan Agreement by March 31, 2020 or that next fiscal year, and if the Company fails to refinance the 2017 Secured Loan Agreement, the Company must notify Oxford of such default and Oxford would be permitted to exercise remedies against us and its assets in respect of such event of default, including taking control of our cash and commencing foreclosure proceedings on our other assets.

The initial principal payment on the 2017 Secured Loan Agreement is due on February 1, 2020. We intend to refinance the 2017 Secured Loan Agreement before the interest only period ends and the principal repayments begin in January 2020. We may not be able to refinance or 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. If we are unable to refinance the 2017 Secured Loan Agreement before the interest only period ends

or shortly thereafter, then we will be required to make principal repayments beginning in January 2020 which will require us to raise additional capital through the sale of equity and the ownership interest of our stockholders will be diluted. 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.

In January 2017, the Company 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 the Company 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 its own account in one or more offerings. On May 10, 2017, the Company filed with the SEC a prospectus supplement (the “Prospectus Supplement”) for the sale and issuance of up to $50 million of its common stock and entered into a Distribution Agreement ("Distribution Agreement") with Canaccord Genuity, Inc. , or Canaccord, pursuant to which Canaccord agreed to sell shares of the Company's common stock from time to time, as our agent, in an “at-the-market” offering ("ATM") as defined in Rule 415 promulgated under the U.S. Securities Act of 1933, as amended. The Company is not obligated to sell any shares under the Distribution Agreement. As of December 31, 2018, the Company has sold 785,280 Shares under the Distribution Agreement resulting in net proceeds of $1.5 million.

On January 29, 2018, the Company closed an offering of its common stock off of its shelf registration statement and issued and sold 15,333,333 shares of its 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. The Company used the net proceeds of the offering of the shares for general corporate purposes, which included research and development costs, sales and marketing costs, clinical studies, manufacturing development, the acquisition or licensing of other businesses or technologies, repayment and refinancing of debt, including the Company's secured term loan facility, working capital and capital expenditures.

In addition, the Smith & Nephew settlement and license agreement, discussed in Note J-Commitments and Contingencies, Legal proceedings, provided the Company with $10.5 million of royalty revenue for the year ended December 31, 2018.

On December 17, 2018, the Company entered into a stock purchase agreement with Lincoln Park Capital ("LPC" and the "LPC Agreements"). Upon entering the LPC Agreements, the Company sold 1,921,968 shares of common stock for $1.0 million to LPC, representing a premium of 110% to the previous day's closing price. As consideration for LPC’s commitment to purchase shares of common stock under the LPC Agreements, Conformis has issued 354,430 shares to LPC. The Company has the right at its sole discretion to sell to LPC up to $20.0 million worth of shares over a 36-month period subject to the terms of the LPC Agreements. Conformis will control the timing of any sales to LPC and LPC will be obligated to make purchases to Conformis common stock upon receipt of requests from Conformis in accordance with the terms of the agreements. There are no upper limits to the price per share LPC may pay to purchase the up to $20.0 million worth of common stock subject to the Agreements, and the purchase price of the shares will be based on the then prevailing market prices of the Company’s shares at the time of each sale to LPC as described in the LPC Agreements, provided that LPC will not be obligated to make purchases of our common stock pursuant to receipt of a request from us on any business day on which the last closing trade price of our common stock on the Nasdaq Capital Market (or alternative national exchange in accordance with the LPC Agreements) is below a floor price of $0.25 per share. No warrants, derivatives, financial or business covenants are associated with the LPC Agreements and LPC has agreed not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of shares of the Company’s common stock. The LPC Agreements may be terminated by the Company at any time, at its sole discretion, without any cost or penalty.

The Company expects that its existing cash and cash equivalents and investments as of December 31, 2018, anticipated revenue from operations, and the ability to issue equity to LPC will enable the Company to fund its

operating expenses and capital expenditure requirements and for at least the next 12 months from the date of filing. Management has based this expectation on assumptions that may prove to be wrong, such as the revenue that it expects to generate from the sale of its products, the gross profit the Company expects to generate from that revenue, the reduction in operating expenses beginning in 2019, and it could use its capital resources sooner than we expect.

The Company anticipates that its principal sources of funds in the future will be revenue generated from the sales of its products, potential future capital raises through the issuance of equity or other securities, potential debt

financings, and revenue that may be generated in connection with licensing its intellectual property. When the Company needs additional equity or debt financing proceeds to fund its operations, whether within the next 12 months or later, the Company may not be able to obtain additional financing on terms favorable to the Company, or at all.

Basis of presentation and use of estimates

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

Note B—Summary of Significant Accounting Policies

Concentrations of credit risk and other risks and uncertainties

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

The Company and its contract manufacturers rely on sole source suppliers and service providers for certain components. There can be no assurance that a shortage or stoppage of shipments of the materials or components that the Company purchases will not result in a delay in production or adversely affect the Company's business. On an on-going basis, the Company validates alternate suppliers relative to certain key components as needed.

For the years ended December 31, 2018, 2017 and 2016, no customer represented greater than 10% of revenue. There were no customers that represented greater than 10% of total gross receivable balance at December 31, 2018 and 2017.

Principles of consolidation

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

Cash and cash equivalents

The Company considers all highly liquid investment instruments with original maturities of 90 days or less when purchased, to be cash equivalents. The Company's cash equivalents consist of demand deposits, money market accounts and repurchase agreements on deposit with certain financial institutions, in addition to cash deposits in excess of federally insured limits. Demand deposits are carried at cost which approximates their fair value. Money market accounts are carried at fair value based upon level 1 inputs. Repurchase agreements are valued using level 2 inputs. See "Note C — Fair Value Measurements" below. The associated risk of concentration is mitigated by banking with credit worthy financial institutions.

The Company had $1.1 million as of December 31, 2018 and $2.2 million as of December 31, 2017 held in foreign bank accounts, that was not federally insured. In addition, the Company has recorded restricted cash of $0.5 million as

of December 31, 2018 and 2017. Restricted cash consisted of security provided for lease obligations.

Investment securities

The Company classifies its investment securities as available-for-sale. Those investments with maturities less than 12 months at the date of purchase are considered short-term investments. Those investments with maturities greater than 12 months at the date of purchase are considered long-term investments. The Company's

investment securities classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses, deemed temporary in nature, are reported as a separate component of accumulated other comprehensive income (loss).

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

Fair value of financial instruments

Certain of the Company’s financial instruments, including cash and cash equivalents (excluding money market funds), accounts receivable, accounts payable, accrued expenses and other liabilities are carried at cost, which approximates their fair value because of the short-term maturity. The carrying value of the debt approximates fair value because the interest rate under the obligation approximates market rates of interest available to the Company for similar instruments.

Accounts receivable and allowance for doubtful accounts

Accounts receivable consist of billed and unbilled amounts due from medical facilities. Upon completion of a procedure and revenue is recognized and an unbilled receivable is recorded. Under ASC 606, an enforceable contract is met either at or prior to the procedure being performed. Upon receipt of a purchase order number from a medical facility a billed receivable is recorded and the unbilled receivable is reversed. As a result, the unbilled receivable balance fluctuates based on the timing of the Company's receipt of purchase order numbers from the medical facilities. In estimating whether accounts receivable can be collected, the Company performs evaluations of customers and continuously monitors collections and payments and estimates an allowance for doubtful accounts based on the aging of the underlying invoices, collections experience to date and any specific collection issues that have been identified. The allowance for doubtful accounts is recorded in the period in which revenue is recorded or when collection risk is identified.

Inventories

Inventories consist of raw materials, work-in-process components and finished goods. Inventories are stated at the lower of cost, determined using the first-in first-out method, or net realizable value. The Company regularly reviews its inventory quantities on hand and related cost and records a provision for any excess or obsolete inventory based on its estimated forecast of product demand and existing product configurations. The Company also reviews its inventory value to determine if it reflects the lower of cost or market based on net realizable value. Appropriate consideration is given to inventory items sold at negative gross margin, purchase commitments and other factors in evaluating net realizable value. During the years ended December 31, 2018, 2017 and 2016, the Company recognized provisions of $1.9 million, $2.6 million and $3.5 million, respectively, to adjust its inventory value to the lower of cost or net realizable value for estimated unused product related to known and potential cancelled cases, which is included in cost of revenue.

Property and equipment

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

Maintenance and repair costs are expensed as incurred.

Business combinations and purchase accounting

The Company includes the results of operations of the businesses that it acquires as of the applicable acquisition date. The purchase price of the acquisition is allocated to the assets acquired and liabilities assumed based on their estimated fair values. The excess of the purchase price over the fair values of these identifiable assets and liabilities is recorded as goodwill. Acquisition-related expenses are recognized separately from the business combination and are expensed as incurred.

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Goodwill

Goodwill relates to amounts that arose in connection with the acquisition of ImaTx, Inc. in 2009 and the acquisition of BPM in August 2017. The Company tests goodwill at least annually for impairment, or more frequently when events or changes in circumstances indicate that the assets may be impaired. This impairment test is performed annually during the fourth quarter at the reporting unit level. Goodwill may be considered impaired if the carrying value of the reporting unit, including goodwill, exceeds the reporting unit's fair value. The Company is comprised of one reporting unit. When testing goodwill for impairment, the Company first assesses the qualitative factors to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount. This qualitative analysis is used as a basis for determining whether it is necessary to perform the one-step goodwill impairment analysis. If the Company determines that it is more likely than not that its fair value is less than its carrying amount, then the one-step goodwill impairment test will be performed. During the three months ended September 30, 2018, the Company's qualitative analysis indicated a triggering event required a step one analysis to determine the fair value of the reporting unit for the period ended September 30, 2018. The Company's drop in market capitalization and decrease in cash flow position were indicators of impairment. The Company determined the fair value of the reporting unit using the combination of its market capitalization, income approach, and the merger and acquisition method concluding that the fair value of the reporting unit is less than the carrying amount in excess of Goodwill, therefore fully impairing Goodwill. During the year ended December 31, 2017, there were no triggering events which would require goodwill impairment assessment.

The changes in the carrying amount of goodwill are as follows:

	December 31, 2018	December 31, 2017
Beginning Balance	6,731	753
Acquired	—	5,978
Impairment	(6,731)	—
Ending Balance	—	6,731

Intangibles and other long-lived assets

Intangible assets consist of developed technology acquired as part of the ImaTx spin-out transaction in 2004 and a favorable lease asset from the Broad Peak Manufacturing, LLC, or BPM, acquisition in August 2017. Intangible assets are carried at cost less accumulated amortization.

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

Furthermore, periodically the Company assesses whether long-lived assets, including intangible assets, should be tested for recoverability whenever events or circumstances indicate that their carrying value may not be recoverable. To evaluate for impairment, the Company compares the undiscounted cash flows to be generated from such assets or groups of assets to the carrying value. If the undiscounted cash flows are less than the carrying value, the amount of impairment is measured based on fair value. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, the Company may be required to record impairment charges. In 2018, the Company recognized $2.4 million in impairment charges, comprised of $1.9 million related to unused manufacturing equipment abandoned in July, $0.3 million related to the expiration of a credit towards a purchase of certain manufacturing equipment, and the remaining $0.2 million impairment charges relate primarily to the discontinuance of software applications. In 2017, the Company recognized $1.1 million in impairment charges of which $0.8 million

related to the discontinuance of a software capital project and $0.3 million related to intellectual property rights licensed as part of the ImaTx spin-out transaction in 2004. In 2016, a $0.1 million impairment charge was recognized in connection with certain manufacturing equipment previously purchased that will be returned to the seller in exchange for credit toward a future purchase, which value is less than the book value of the equipment. Impairment charges are included in General and administrative expense.

Revenue recognition

The Company adopted ASU No. 2014-9, “Revenue from Contracts with Customers (ASC 606)” as of January 1, 2018. Based on the Company's assessment, generally revenue recognition from the sale of its products to customers effectively remains unaffected by the adoption of ASC 606. The assessment of the royalty revenue associated with the Company's 2015 license agreements previously entered into with Wright Medical Group Inc. and MicroPort Orthopedics, Inc. was affected by the adoption of ASC 606. Previously, under ASC 605, the Company recognized an initial $5.1 million, in aggregate, as deferred royalty revenue under these agreements, to be recognized ratably through 2027 and 2031 for Wright Medical Group Inc. and MicroPort Orthopedics, Inc., respectively. The Company's analysis of these contracts indicated that under ASC 606 the licenses are functional and thus revenue would have been recognized in full on the execution date. Further the ongoing royalty from MicroPort was previously recognized as royalty revenue upon receipt of payment. Under ASC 606, royalty is recognized in the period the sale occurred. The Company elected to apply the adoption of ASC 606 using the modified retrospective method for contracts that were not complete as of December 31, 2017, resulting in an adjustment to the 2018 opening balance of accumulated deficit to recognize the deferred royalty revenue immediately. Comparative information has not been restated and continues to be reported under the accounting policy in effect for those periods, including ASC 605, Revenue Recognition.

The following table summarizes the balance sheet adjustments upon adoption of ASC 606 (in thousands):

	As Reported December 31, 2017	Balance at January 1, 2018	ASC 606 Adjustment	
Current Assets				
Royalty receivable	$ —	$ 200	$ 200	(1)
Current liabilities				
Deferred revenue	305	—	(305)	(2)
Long-term liabilities				
Deferred revenue	4,014	—	(4,014)	(2)
Stockholders' equity				
Accumulated deficit	(436,821)	(432,302)	(4,519)	(1),(2)

(1) MicroPort sales-based royalty recognized in period earned under Topic 606, previously recognized when cash received and amortization of deferred royalty revenue.

(2) Wright Medical and MicroPort royalty deferred and recognized ratably through 2027 and 2031, respectively, under Topic 605, recognized in full at contract inception date under Topic 606.

The following table summarizes the effect of ASC 606 on the Company's consolidated financial statements as of December 31, 2018 (in thousands, except per share amounts):

Balance Sheet	As Reported	Pro-forma [1]	Effect	
Current Assets				
Royalty receivable	$ 145	$ —	$ 145	[2]
Current liabilities				
Deferred revenue	—	305	(305)	[3]
Long-term liabilities				
Deferred revenue	—	3,709	(3,709)	[3]
Stockholders' equity				
Accumulated deficit	(475,667)	(471,507)	4,160	[2],[3]

Statement of Operations	As Reported	Pro-forma [1]	Effect	
Revenue				
Royalty	$ 11,162	$ 11,521	$ (359)	[2],[3]
Net Loss	(43,365)	(43,006)	(359)	[2],[3]
Net loss per share - basic and diluted	$ (0.74)	$ (0.73)	$ (0.01)	

Statement of Cash Flows	As Reported	Pro-forma [1]	Effect	
Cash flows form operating activities:				
Net loss	$ (43,365)	$ (43,006)	$ (359)	[2],[3]
Changes in operating assets and liabilities	(26,982)	(27,341)	359	[2],[3]

(1) Pro-forma balances without adoption of ASC 606.
(2) Effect relates to MicroPort sales-based royalty recognized in period earned under Topic 606, previously recognized when cash received and amortization of deferred royalty revenue.
(3) Effect relates to Wright Medical and MicroPort royalty deferred and recognized ratably through 2027 and 2031, respectively, under Topic 605, recognized in full at contract inception date under Topic 606.

Revenue Recognition

Revenue is recognized when, or as, obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer (“transaction price”). When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company’s contracts contained a significant financing component as of December 31, 2018. Payment is typically due between 30 - 60 days from invoice.

To the extent that the transaction price includes variable consideration, such as prompt-pay discounts or rebates, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value to which the Company expects to be entitled. Variable consideration is included in the transaction price if, in the Company’s judgment, it is probable that a significant future reversal of cumulative revenue under the

contract will not occur. Actual amounts of consideration ultimately received may differ from the Company's estimates. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company’s anticipated performance and all information (historical, current and forecasted) that is reasonably available.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the

transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on observable prices or a cost-plus margin approach when one is not available. Revenue is recognized at the time the related performance obligation is satisfied by transferring control of a promised good or service to a customer. The Company's performance obligations are satisfied at the same time, typically upon surgery, therefore, product revenue is recognized at a point in time upon completion of the surgery. Since the Company does not have contracts that extend beyond a duration of one year, there is no transaction price related to performance obligations that have not been satisfied.

Certain customer contracts include terms that allow the Company to bill for orders that are cancelled after the product is manufactured and could result in revenue recognition over time. However, the impact of applying over time revenue recognition was deemed immaterial.

The Company does not have any contract assets or liabilities with customers. Unconditional rights to consideration are reported as receivables. Incidental items that are immaterial in the context of the contract are recognized as expense.

Disaggregation of Revenue

See "Note O—Segment and Geographic Data" for disaggregated product revenue by geography.

Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from rebates that are offered within contracts between the Company and some of its customers. The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The following table summarizes activity for rebate allowance reserve for the year ended December 31, 2018 (in thousands):

	December 31, 2018
Beginning Balance	$ 119
Provision related to current period sales	129
Adjustment related to prior period sales	40
Payments or credits issued to customer	(192)
Ending Balance	$ 96

Costs to Obtain and Fulfill a Contract

The Company currently expenses commissions paid for obtaining product sales. Sales commissions are paid following the manufacture and implementation of the implant. Due to the period being less than one year, the Company will apply the practical expedient, whereby the Company recognizes the incremental costs of obtaining contracts as an expense when incurred if the amortization period of the assets that the Company otherwise would have recognized is one year or less. These costs are included in sales and marketing expense. Further, the Company incurs costs to buy, build, replenish, restock, sterilize and replace the reusable instrumentation trays associated with the sale of its products and services. The reusable instrument trays are not contract specific and are used for multiple contracts and customers, therefore does not meet the criteria to capitalize.

Shipping and handling costs

Shipping and handling activities prior to the transfer of control to the customer (e.g. when control transfers after delivery) are considered fulfillment activities, and not performance obligations. Amounts invoiced to customers for shipping and handling are classified as revenue. Shipping and handling costs incurred are included in

general and administrative expense. Shipping and handling expense was $1.6 million, $1.4 million and $1.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Taxes collected from customers and remitted to government authorities

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

Research and development expense

The Company's research and development costs consist of engineering, product development, quality assurance, clinical and regulatory expense. These costs primarily relate to employee compensation, including salary, benefits and stock-based compensation. The Company also incurs costs related to consulting fees, materials and supplies, and marketing studies, including data management and associated travel expense. Research and development costs are expensed as incurred.

Advertising expense

Advertising costs are expensed as incurred, which are included in sales and marketing. Advertising expense was $0.7 million for the year ended December 31, 2018, $0.4 million for the year ended December 31, 2017 and $0.3 million for the year ended December 31, 2016.

Segment reporting

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

Comprehensive loss

At December 31, 2018 and 2017, accumulated other comprehensive loss consists of foreign currency translation adjustments and changes in unrealized gain and loss of available-for-sale securities, net of tax. The following table summarizes accumulated beginning and ending balances for each item in Accumulated other comprehensive income (loss) (in thousands):

	Foreign currency translation adjustments	Change in unrealized gain (loss) on available-for-sale securities, net of tax	Accumulated other comprehensive income (loss)
Balance December 31, 2017	$ (3,203)	$ (33)	$ (3,236)
Change in period	1,733	33	1,766
Balance December 31, 2018	$ (1,470)	$ —	$ (1,470)

Foreign currency translation and transactions

The assets and liabilities of the Company’s foreign operations are translated into U.S. dollars at current exchange rates at the balance sheet date, and income and expense items are translated at average rates of exchange prevailing during the year. Net translation gains and losses are recorded in Accumulated other comprehensive (loss) income. Gains and losses realized from transactions denominated in foreign currencies, including intercompany balances not of a long-term investment nature, are included in the consolidated statements of operations.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period that includes the enactment date.

In evaluating the need for a valuation allowance, the Company considers all reasonably available positive and negative evidence, including recent earnings, expectations of future taxable income and the character of that income. In estimating future taxable income, the Company relies upon assumptions and estimates of future activity including the reversal of temporary differences. Presently, the Company believes that a full valuation allowance is required to reduce deferred tax assets to the amount expected to be realized.

The tax benefit from an uncertain tax position is only recognized if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from these positions are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. The Company reviews its tax positions on an annual basis and more frequently as facts surrounding tax positions change. Based on these future events, the Company may recognize uncertain tax positions or reverse current uncertain tax positions, the impact of which would affect the consolidated financial statements.

The Company has operations in Germany and, until July 1,2017, the United Kingdom. The operating results of these operations will be permanently reinvested in those jurisdictions. As a result, the Company has only provided for income taxes at local rates when required.

Accounting Standard Update ("ASU") No. 2016-09, "Compensation - Stock Compensation", was issued and adopted in January 2017. ASU 2016-09 eliminates additional paid in capital ("APIC") pools and requires excess tax benefits and tax deficiencies to be recorded in the income statement when the awards vest or are settled. In addition, modified retrospective adoption of ASU 2016-09 eliminates the requirement that excess tax benefits be realized (i.e., through a reduction in income taxes payable) before the Company can recognize them and therefore, it has accounted for a cumulative-effect adjustment of $7.7 million during the year ended December 31, 2018 to record excess tax benefits. Since the Company has a full valuation allowance on all deferred taxes, this has no impact on retained earnings or the tax position of the Company.

On December 22, 2017, H.R. 1, known as the Tax Cuts and Jobs Act, was signed into law, which includes a broad range of topics affecting corporations – including corporate tax rates, business deductions and international provisions. The effect of the tax law changes has been recognized in the Company's December 31, 2018 financial statements.

Medical device excise tax

The Company has been subject to the Health Care and Education Reconciliation Act of 2010 (the “Act”), which imposes a tax equal to 2.3% on the sales price of any taxable medical device by a medical device manufacturer, producer or importer of such device. Under the Act, a taxable medical device is any device defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act, intended for humans, which includes an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which meets certain requirements. The Consolidated Appropriations Act of 2016 includes a two-year moratorium on the medical device excise tax, which moratorium suspended taxes on the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016 and

ending on December 31, 2017. As such, the Company did not incur medical device excise tax expense for the years ended December 31, 2018, 2017, and 2016.

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.

Stock-based compensation

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

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

Net loss per share

The Company calculates net loss per share in accordance with ASC 260, "Earnings per Share". Basic earnings per share (“EPS”) is calculated by dividing the net income or loss for the period by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted EPS is computed by dividing the net income or loss for the period by the weighted average number of common shares outstanding for the period and the weighted average number of dilutive common stock equivalents outstanding for the period determined using the treasury stock method.

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

	Years Ended December 31,		
(in thousands, except share and per share data)	2018	2017	2016
Numerator:			
Numerator for basic and diluted loss per share:			
Net loss	$(43,365)	$(53,580)	$(57,588)
Denominator:			
Denominator for basic loss per share:			
Weighted average shares	58,886,333	43,343,459	41,521,629
Basic loss per share attributable to Conformis, Inc. stockholders	$(0.74)	$(1.24)	$(1.39)
Diluted loss per share attributable to Conformis, Inc. stockholders	$(0.74)	$(1.24)	$(1.39)

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

	Years Ended December 31,		
	2018	2017	2016
Common stock warrants	—	—	34,709
Stock options	55,346	365,105	1,959,030
Total	55,346	365,105	1,993,739

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Recent accounting pronouncements

In August 2018, the FASB issued ASU No. 2018-15, "Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract". Under the new guidance, implementation costs should be evaluated for capitalization using the same approach as implementation costs associated with internal-use software and should be expensed over the term of the hosting arrangement, including any reasonably certain renewal periods. This ASU is effective for fiscal years beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period. Prospective adoption for eligible costs incurred on or after the date of adoption or retrospective adoption are permitted. The Company does not expect the adoption of ASU 2018-15 will have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement". This ASU modifies disclosure requirements relative to the three levels of inputs used to measure fair value in accordance with Topic 820. This ASU is effective for fiscal years beginning after December 15, 2019, including interim periods. Early adoption is permitted for any eliminated or modified disclosures. The Company does not expect the adoption of ASU 2018-13 will have a material impact on its consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-09, "Codification Improvements". This ASU makes amendments to multiple codification Topics and the transition and effective date is based on the facts and circumstances of each amendment. Many of the amendments in this ASU have transition guidance with effective dates for annual periods beginning after December 15, 2018. The Company is currently evaluating the impact of the pronouncement on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting." This ASU supersedes Subtopic 505-50, "Equity - Equity-Based Payments to Non-Employees" and expands on the scope of Topic 718, "Compensation - Stock Compensation", to include share-based payments issued to nonemployees for goods or services. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. The Company does not expect the adoption of ASU 2018-07 will have a material impact on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, "Credit Losses (Topic 326)." ASU 2016-13 requires that financial assets measured at amortized cost, such as trade receivables, be represented net of expected credit losses, which may be estimated based on relevant information such as historical experience, current conditions, and future expectation for each pool of similar financial asset. The new guidance requires enhanced disclosures related to trade receivables and associated credit losses. The guidance is effective beginning January 1, 2020. The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)." This ASU amends various aspects of existing guidance for leases and requires additional disclosures about leasing arrangements. It will require companies to recognize lease assets and lease liabilities by lessees for those leases classified as operating leases under GAAP. Topic 842 retains a distinction between finance leases and operating leases. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous leases guidance. This ASU is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years; earlier adoption is permitted. In the financial statements in which the ASU is first applied, leases shall be measured and recognized at the beginning of the earliest comparative period presented with an adjustment to equity. Practical expedients are available for election as a package and if applied consistently to all leases. In July 2018, the FASB issued ASU No. 2018-11, "Leases (Topic 842): Targeted Improvements" which allows entities the option not to recast

the comparative periods presented when transitioning to Topic 842. The Company has completed its assessment to evaluate the impact on its consolidated financial statements. The Company will adopt this pronouncement and related disclosures commencing in the first quarter of 2019. The Company will elect the 'package of practical expedients' and carry over our prior conclusions about lease identification, lease classification and initial direct costs. The Company expects that, based on its assessment, the most significant effect will relate to the recognition of new right of use assets and lease liabilities in a range of approximately $7 million to $8 million related to the Company's real estate operating leases on the Balance Sheet. The Company has also completed its evaluation of changes to its processes and internal controls, as necessary, to meet the requirements.

Note C—Fair Value Measurements

The Fair Value Measurements topic of the FASB Codification establishes a framework for measuring fair value in accordance with US GAAP, clarifies the definition of fair value within that framework and expands disclosures about fair value measurements. This guidance requires disclosure regarding the manner in which fair value is determined for assets and liabilities and establishes a three-tiered value hierarchy into which these assets and liabilities must be grouped, based upon significant levels of inputs as follows:
Level 1—Quoted prices in active markets for identical assets or liabilities.
Level 2—Observable inputs, other than Level 1 prices, such as quoted prices in active markets for similar assets and liabilities, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.
Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

The Company's investment policy is consistent with the definition of available-for-sale securities. All investments have been classified within Level 1 or Level 2 of the fair value hierarchy because of the sufficient observable inputs for revaluation. The Company's Level 1 cash and equivalents and investments are valued using quoted prices that are readily and regularly available in the active market. The Company's Level 2 investments are valued using third-party pricing sources based on observable inputs, such as quoted prices for similar assets at the measurement date; or other inputs that are observable, either directly or indirectly.

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

December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and cash equivalents	Short-term (1) investments
Cash	$ 9,837	$ —	$ —	$ 9,837	$ 9,837	$ —
Level 1 securities:						
Money market funds	1,046	—	—	1,046	1,046	—
U.S. treasury bonds	10,494	—	—	10,494	5,497	4,997
Level 2 securities:						
Corporate bonds	1,249	—	—	1,249	—	1,249
Commercial paper	999	—	—	999	—	999
Total	$ 23,625	$ —	$ —	$ 23,625	$ 16,380	$ 7,245

December 31, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and cash equivalents	Short-term (1) investments
Cash	$ 9,849	$ —	$ —	$ 9,849	$ 9,849	$ —
Level 1 securities:						
Money market funds	3,499	—	—	3,499	3,499	—
U.S. treasury bonds	9,243	—	(4)	9,239	—	9,239
Level 2 securities:						
Corporate bonds	4,935	—	(6)	4,929	—	4,929
Commercial paper	—	—	—	—	—	12,712
Agency bonds	12,734	—	(22)	12,712	—	—
Repurchase agreement	$ 5,000	$ —	$ —	$ 5,000	$ 5,000	
Total	$ 45,260	$ —	$ (32)	$ 45,228	$ 18,348	$ 26,880

(1) Contractual maturity due within one year.

Note D—Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	December 31, 2018	December 31, 2017
Total receivables	$ 13,634	$ 13,835
Allowance for doubtful accounts and returns	(390)	(635)
Accounts receivable, net	$ 13,244	$ 13,200

Accounts receivable included unbilled receivable of $2.2 million and $1.4 million for the years ended December 31, 2018 and 2017. Write-offs related to accounts receivable were approximately $115,000, $92,000, and $41,000 for the years ended December 31, 2018, 2017, and 2016, respectively.

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

	December 31, 2018	December 31, 2017
Beginning balance	$ (635)	$ (681)
Provision for bad debts on trade receivables	72	15
Other allowances	58	(61)
Accounts receivable write offs	115	92
Ending balance	$ (390)	$ (635)

Note E—Inventories

Inventories consisted of the following (in thousands):

	December 31, 2018	December 31, 2017
Raw Material	$ 4,498	$ 2,905
Work in process	1,518	1,718
Finished goods	3,518	4,561
Total Inventories	$ 9,534	$ 9,184

Note F—Acquisition

On August 9, 2017, the Company completed the purchase of certain assets and assumed certain liabilities of Broad Peak Manufacturing, LLC, or BPM, for approximately $6.4 million. Of the total purchase price paid, $5.8 million was in cash and $0.6 million of unregistered shares of common stock. The purchase was treated as a business combination as it met certain criteria stipulated in ASC 805 - Business Combinations. Prior to the acquisition, BPM provided substantially all of the polishing services for the Company’s femoral implant component. The Company expects the acquisition of the BPM assets will reduce the cost of polishing and improve overall gross margin.

The Company completed the BPM purchase price allocation. Of the total purchase price, approximately $2.2 million related to earn out provisions tied to certain employee retention by the Company and achieving certain cost targets that was paid into an escrow account. An additional $0.7 million could be earned by BPM if the actual cost targets are exceeded. Alternatively, the earn out provisions could be paid back to the Company if the employee retention and cost targets are not achieved. On August 16, 2018, $910,000 related to employee retention was released from the escrow account, and on September 21, 2018, $1.3 million related to the earn out was released from the escrow account which satisfied the earn out provisions.

Of the total purchase price of $6.4 million, $0.4 million was attributed to property and equipment, $6.0 million was attributed to goodwill and less than $0.1 million to other net assets acquired. Goodwill is primarily attributable to the future cost savings expected to arise after the acquisition and is deductible for tax purposes. During the quarter ended September 30, 2018, the Company fully impaired goodwill recognized in the BPM

acquisition. Refer to "Note B—Summary of Significant Accounting Policies" for more information on Goodwill impairment.

The acquisition of BPM is strategically significant in reducing the manufacturing costs for the Company, however at the time of the acquisition and on December 31, 2017, the Company concluded that historical results of the BPM both individually and in the aggregate, were immaterial to the Company's consolidated financial results and therefore additional pro-forma disclosures are not presented.

Note G—Property and Equipment

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

	Estimated Useful Life (Years)	December 31, 2018	December 31, 2017
Equipment	5-7	$ 18,602	$ 19,331
Furniture and fixtures	5-7	954	955
Computer and software	3	8,783	7,877
Leasehold improvements	3-7	1,978	1,830
Reusable instruments	5	1,573	—
Total property and equipment		31,890	29,993
Accumulated depreciation		(17,451)	(13,479)
Property and equipment, net		$ 14,439	$ 16,514

During the first quarter of 2018, the Company substantially completed the reusable instrumentation tray design and commenced capitalization.

Depreciation expense related to property and equipment was $4.0 million, $3.4 million and $2.9 million for the years ended December 31, 2018, 2017 and 2016, respectively. In 2018, the Company recognized $2.4 million in impairment charges, comprised of $1.9 million related to unused manufacturing equipment abandoned in July, $0.3 million related to the expiration of a credit towards a purchase of certain manufacturing equipment, and the remaining $0.2 million impairment charges relate primarily to the discontinuance of software applications. In 2017, the Company recognized $1.1 million in impairment charges of which $0.8 million related to the discontinuance of a software capital project and $0.3 million related to intellectual property rights licensed as part of the ImaTx spin-out transaction in 2004. In 2016, a $0.1 million impairment charge was recognized in connection with certain manufacturing equipment previously purchased that will be returned to the seller in exchange for credit toward a future purchase, which value is less than the book value of the equipment.

Note H—Intangible Assets

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

	Estimated Useful Life (Years)	December 31, 2018	December 31, 2017
Developed technology	10	$ 979	$ 979
Accumulated amortization		(881)	(783)
Developed technology, net		98	196
Acquired favorable lease	5	15	15
Accumulated amortization		(4)	(1)
Acquired favorable lease, net		11	14

Intangible assets, net	$ 109	$ 210

The Company recognized amortization expense of $0.1 million, $0.2 million, and $0.2 million in the years ended December 31, 2018, 2017 and 2016. The weighted-average remaining life of total amortizable intangible assets is 1.3 years for the developed technology and favorable lease asset. In the year ended December 31, 2017, the Company recorded an impairment charge of $0.3 million in general and administration expense in connection with the termination of the license agreements. See “Note B—Summary of Significant Accounting Policies ” to the

financial statements in this Annual Report on Form 10-K for a full description of the impairment charges related to intellectual property rights licensed as part of the ImaTx spin-out transaction in 2004.

The estimated future aggregated amortization expense for intangible assets owned as of December 31, 2018 consisted of the following (in thousands):

	Amortization expense
2019	$ 101
2020	3
2021	3
2022	2
	$ 109

Note I—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2018	December 31, 2017
Accrued employee compensation	$ 3,138	$ 2,989
Deferred rent	132	115
Accrued legal expense	215	1,231
Accrued consulting expense	84	115
Accrued vendor charges	1,441	912
Accrued revenue share expense	1,134	968
Accrued clinical trial expense	549	196
Accrued other	1,237	1,194
	$ 7,930	$ 7,720

Note J—Commitments and Contingencies

Operating Leases - Real Estate

The Company maintains its corporate headquarters in a leased building located in Billerica, Massachusetts. The Company moved its corporate headquarters from Bedford, Massachusetts in April 2017. The Company maintains its manufacturing facilities in leased buildings located in Wilmington, Massachusetts and Wallingford, Connecticut.

The Billerica facility is leased under a long-term, non-cancellable lease that is scheduled to expire in October 2025. The Company has a right to extend the term for two successive five year terms following the termination of the lease.

The Company leases its Wilmington, Massachusetts facility under a long-term, non-cancellable lease that commenced in April 2015 and will expire in July 2022 (the "Wilmington Lease"). The Company also rents a satellite facility under short-term non-cancellable operating lease. On July 25, 2016, the Company entered into an amendment to the Wilmington Lease. Pursuant to the amendment, the Company exercised an option in its current lease to rent an additional 18,223 square feet of space adjacent to the Company’s existing premises. The Company took possession of the additional space in April 2017. The Company has a right to extend the term for one additional five-year period following termination of the lease in July 2022. The initial base rental rate for the additional space is $0.2 million annually, subject to 2% annual increases until the expiration of the initial term.

On August 9, 2017, the Company entered into a lease for 4,099 square feet of space in Wallingford, Connecticut which houses the polishing and passivation processes. The lease term is five years with the option to extend for two

additional years beyond the original term and an additional three years past the first extension term.

The future minimum rental payments under the Company’s non-cancellable operating leases for real estate as of December 31, 2018 were as follows (in thousands):

Year	Minimum lease Payments
2019	$ 1,558
2020	1,595
2021	1,633
2022	1,397
2023-2025	2,939
	$ 9,122

Rent expense of $1.5 million, $1.7 million, and $1.5 million for the years ended December 31, 2018, 2017, and 2016, respectively, and was charged to operations. The Company's real estate operating lease agreements contain scheduled rent increases, which are being amortized over the terms of the agreements using the straight-line method. Deferred rent was $0.7 million, $0.8 million, and $0.3 million as of December 31, 2018, 2017, and 2016, respectively. Deferred rent is included in accrued expenses and other long-term liabilities.

License and revenue share agreements

Revenue share agreements

The Company is party to revenue share agreements with certain past and present members of its scientific advisory board under which these advisors agreed to participate on its scientific advisory board and to assist with the development of the Company's customized implant products and related intellectual property. These agreements provide that the Company will pay the advisor a specified percentage of the Company's net revenue, ranging from 0.1% to 1.33%, with respect to the Company's products on which the advisor made a technical contribution or, in some cases, which the Company covered by a claim of one of its patents on which the advisor is a named inventor. The specific percentage is determined by reference to product classifications set forth in the agreement and may be tiered based on the level of net revenue collected by the Company on such product sales. The Company's payment obligations under these agreements typically expire a fixed number of years after expiration or termination of the agreement, but in some cases expire on a product-by-product basis or expiration of the last to expire of the Company's patents where the advisor is a named inventor that has claims covering the applicable product.

Philipp Lang, M.D., our former Chief Executive Officer and former director, joined the Company's scientific advisory board in 2004 prior to becoming an employee. The Company first entered into a revenue share agreement with Dr. Lang in 2008 when he became the Company's Chief Executive Officer. In 2011, the Company entered into an amended and restated revenue share agreement with Dr. Lang. Under this agreement, the specified percentage of the Company's net revenue payable to Dr. Lang ranges from 0.875% to 1.33% and applies to all of the Company's current products, including the Company's iUni, iDuo, iTotal CR, iTotal PS, and Conformis Hip System products, as well as certain other knee, hip and shoulder replacement products and related instrumentation the Company may develop in the future. The Company's payment obligations under this agreement expire on a product-by-product basis on the last to expire of the Company's patents on which Dr. Lang is named an inventor that has a claim covering the applicable product. These payment obligations survived the termination of Dr. Lang's employment with the Company. We have raised concerns with Dr. Lang relating to this revenue share agreement and have been seeking to enter into discussion with Dr. Lang concerning the scope of this agreement. In October of 2018, we requested that Dr. Lang provide consulting services as permitted under Dr. Lang's revenue share agreement. However, he failed to respond to such request and, as a result, beginning in the fourth quarter of 2018, the revenue share percentage rate owed to Dr. Lang has been reduced by 50% within the scope of his agreement. The Company incurred revenue share expense for Dr. Lang of $0.7 million, $1.0 million and $1.0 million for the years ended December 31, 2018, 2017 and 2016, respectively.

The Company incurred aggregate revenue share expense including all amounts payable under the Company's scientific advisory board and Dr. Lang revenue share agreements of $3.1 million during the year ended December 31, 2018, representing 4.0% of product revenue, $3.7 million during the year ended December 31, 2017, representing 4.8% of product revenue, and $3.5 million during the year ended December 31, 2016, representing 4.4% of product revenue. Revenue share expense is included in research and development. See "Note L—Related Party Transactions" for further information regarding the Company's arrangement with Dr. Lang.

Other obligations

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

The following table summarizes the Company's contractual obligations as of the year ended December 31, 2018 (in thousands):

	Payment Due by Period				
	Total	Less than 1 year	Years 1 to 3	Years 3 to 5	After 5 years
Contractual Obligations (1)(2)	$1,355	$526	$650	$179	$ —

(1) Represents amounts payable under our product royalty agreement, operating leases for office equipment, automobile leases, and a software development collaboration project with a remaining term in excess of one year.

(2) This table does not include: (a) revenue share obligations to past and present members of our scientific advisory board and one of our directors, as the amounts of such payments are not known with certainty; and (b) contracts that are entered into in the ordinary course of business that are not material in the aggregate in any period presented above. See "—Revenue share agreements" for a description of our revenue share arrangements.

There have been no contingent liabilities requiring accrual at December 31, 2018 or December 31, 2017.

Legal proceedings

In the ordinary course of the Company's business, the Company is 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 the Company sells its products.

On February 29, 2016, the Company filed a lawsuit against Smith & Nephew, Inc. (“Smith & Nephew”) in the United States District Court for the District of Massachusetts Eastern Division, and the Company amended its 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 implant systems used in conjunction with the Visionaire instrumentation infringe nine of the Company's patents, and it requested, 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 the Company's lawsuit, which it subsequently amended on July 22, 2016. Smith & Nephew denied that its Visionaire® patient-specific instrumentation as well as the implant systems used in conjunction with the Visionaire instrumentation infringe the patents asserted by the Company in the lawsuit. It also alleged two affirmative defenses: that the Company's asserted patents are invalid and that the Company is 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 the Company's patents and that the Company's patents are invalid. Smith & Nephew also alleged that the Company infringed ten patents owned or exclusively licensed by Smith & Nephew: two of those patents Smith & Nephew alleges are infringed by the Company's iUni and iDuo products; three of those patents Smith & Nephew alleges are infringed by the Company's iTotal products; and five of those patents Smith & Nephew licenses from Kinamed, Inc. of Camarillo, California and alleged are infringed by the Company's 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 the Company. With the dismissal of all claims involving Kinamed's patents, Kinamed was no longer a party to the lawsuit.

On January 27, 2017, Smith & Nephew filed a motion seeking a stay of the Smith & Nephew Lawsuit until any requested IPRs (defined and described below) were resolved. On April 27, 2017, the Court stayed certain aspects of the proceedings and indicated that it would make a final decision on the motion to stay after the USPTO has decided more of the petitions for Inter Partes Review (“IPR”).

Between September 21, 2016 and March 1, 2017, Smith & Nephew filed sixteen petitions with the United States Patent & Trademark Office (“USPTO”) requesting IPRs of the nine patents that the Company asserted against Smith & Nephew in the lawsuit. In its petitions, Smith & Nephew alleged that the Company's patents were 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 ("Subject Patent Claims"). On April 24, 2018, the Supreme Court of the United States issued its ruling in SAS Institute, Inc. v. Iancu (the “SAS Decision”) which held that the IPR proceedings cannot be instituted in part and denied in part. In response to the SAS Decision and guidance from the USPTO, the Patent Trial and Appeal Board (“PTAB”) issued an order on April 27, 2018 including the Subject Patent Claims within the prior instituted IPR proceedings. In total, the USPTO instituted IPR proceedings for claims in six of the patents in the Smith & Nephew lawsuit (five patents that were currently asserted, and one of the patents that was voluntarily dismissed from the lawsuit), and denied the petitions for claims in three of the patents (two patents that were currently asserted and one of the patents that was voluntarily dismissed from the lawsuit). Smith & Nephew filed requests for rehearing of three of the petitions that were denied and the PTAB denied those requests. Smith & Nephew filed requests with the USPTO for reexamination of two of the patents for which IPR proceedings were not instituted and the USPTO granted those requests for reexamination. On August 7, 2018 and October 2, 2018, the USPTO ruled in the Company's favor on both reexamination proceedings finding the claims patentable in both patents.

Between December 18, 2017 and April 18, 2018, IPR hearings were held for the six patents for which IPR proceedings were instituted. On March 26, 2018, the USPTO issued its first ruling holding that the Company's U.S. Patent No. 9,055,953 (the “’953 Patent”) is invalid over prior art. On April 19, 2018, the USPTO issued its second ruling holding that the Company's U.S. Patent No. 9,216,025 (the “‘025 Patent”) is invalid over prior art. Following a grant by the U.S. Court of Appeals for the Federal Circuit (the “Federal Circuit”) of the Company's request for consolidation, the Company filed an opening brief on October 1, 2018, appealing the PTAB’s rulings on the ‘953 Patent and the ‘025 patent. On June 11, 2018, the USPTO issued its third ruling holding that a subset of claims in the Company's U.S. Patent No. 7,981,158 (the “‘158 Patent”) are invalid over prior art. On June 12, 2018, the USPTO issued its fourth ruling holding that a subset of claims in the Company's U.S. Patent No. 8,551,169 (the “‘169 Patent”) are invalid over prior art. The ’953 Patent is not part of the lawsuit having been voluntarily dismissed on March 9, 2017. The ‘025, ‘169 and ‘158 Patents were part of the lawsuit. On September 26, 2018, the PTAB terminated the remaining IPR proceedings in response to a joint motion to terminate filed by the Company and Smith & Nephew pursuant to the Settlement and License Agreement (defined and described below).

On September 14, 2018, the Company and Smith & Nephew entered into a Settlement and License Agreement (the “Settlement and License Agreement”) including terms for resolving all of the parties’ existing patent disputes. The Settlement and License Agreement includes terms for dismissal of all outstanding litigation, prohibitions against commencement of litigation with respect to existing product lines, and Smith & Nephew agreed to cease their opposition to certain of the Company's patents currently in IPR proceedings.

Pursuant to the Settlement and License Agreement, the Company granted to Smith & Nephew (i) a fully paid-up, non-exclusive, worldwide license to certain patents for the exploitation of patient-specific instrumentation for use with off-the-shelf knee implants, (ii) a royalty-bearing, non-exclusive, worldwide license to certain patents in the event Smith & Nephew commercializes patient-specific instrumentation for use with off-the-shelf implants other than knee implants, and (iii) a fully paid-up, non-exclusive, worldwide license to certain other patents for exploitation of off-the-shelf implants. Also pursuant to the Settlement and License Agreement, Smith & Nephew granted to the Company a fully paid-up, non-exclusive, worldwide license to certain patents for the exploitation of patient-specific implants and paid the Company $10.5 million. The Company is not required to make a payment to Smith & Nephew.

The foregoing description is qualified in its entirety by reference to the text of the Settlement and License Agreement filed as exhibit 10.1 to the Company's quarterly report on Form 10-Q for the period ended September 30, 2018.

Indemnifications

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

Note K—Debt and Notes Payable

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

	December 31, 2018	December 31, 2017
Term A Loan	$ 7,500	$ 15,000
Term B Loan	7,500	15,000
	15,000	30,000
Less unamortized debt issuance costs	(208)	(333)
Long-term debt, less debt issuance costs	$ 14,792	$ 29,667

Principal payments due as of December 31, 2018 consisted of the following (in thousands):

	Principal Payment
2019	$—
2020	6,875
2021	7,500
2022	625
Total	$ 15,000

2017 Secured Loan Agreement

On January 6, 2017, the Company entered into the 2017 Secured Loan Agreement with Oxford and accessed $15 million under Term Loan A at closing and an additional $15 million of borrowings under the Term B Loan on June 30, 2017. On July 31, 2018, the Company and Oxford entered into a fourth amendment to the 2017 Secured Loan Agreement, or the Fourth Amendment, with Oxford. The Fourth Amendment added the requirement that the Company maintain at least $10 million in cash collateral and required liens on the Company's copyrights, trademarks and patents. Pursuant to the Fourth Amendment, the Company also agreed to pay Oxford a fee of $1 million within 30 days of consummation of a sale of the Company, if such sale occurs prior to the first anniversary of the Company's full repayment of obligations under the 2017 Secured Loan Agreement. In addition, the Fourth Amendment amended the Company's financial covenants, including increasing of the revenue covenant beginning in January 2019. On December 13, 2018, the Company entered into a fifth amendment to the 2017 Secured Loan Agreement, or the Fifth Amendment, with Oxford, and pursuant to the Fifth Amendment, the Company pre-paid $15 million aggregate principal amount of the $30 million outstanding principal amount, as a pro rata portion of the Term A Loan and Term B Loan, together with accrued and unpaid interest thereon and a pro rata prepayment fee. Under the Fifth Amendment,

the Company's cash collateral requirements was reduced to $5 million.

The Fifth Amendment also reduced the revenue milestones through December 31, 2019. New minimum revenue milestones, based on product revenue projections, are to be established prior to the start of 2020 and prior to the start of each fiscal year thereafter by the mutual agreement of Oxford and the Company. If the Company is not able to agree with Oxford on new minimum revenue milestones for 2020 or a fiscal year thereafter, the Company will have to refinance the 2017 Secured Loan Agreement by March 31, 2020 or that next fiscal year, and if the Company fails to refinance the 2017 Secured Loan Agreement, the Company must notify Oxford of such

default and Oxford would be permitted to exercise remedies against the Company and our assets in respect of such event of default, including taking control of our cash and commencing foreclosure proceedings on our other assets. As of December 31, 2018, the Company was not in breach of covenants under the credit facility.

The 2017 Secured Loan Agreement is secured by substantially all of the Company's personal property other than the Company's intellectual property. Under the terms of the 2017 Secured Loan Agreement, the Company cannot grant a security interest in its intellectual property to any other party.

The term loans under the 2017 Secured Loan Agreement bears interest at a floating annual rate calculated at the greater of 30 day LIBOR or 0.53%, plus 6.47%. The Company is required to make monthly interest only payments in arrears commencing on the second payment date following the funding date of each term loan, and continuing on the payment date of each successive month thereafter through and including the payment date immediately preceding the amortization date of February 1, 2020. Commencing on the amortization date, and continuing on the payment date of each month thereafter, the Company is required to make consecutive equal monthly payments of principal of each term loan, together with accrued interest, in arrears, to Oxford. All unpaid principal, accrued and unpaid interest with respect to each term loan, and a final payment in the amount of 5.0% of the amount of loans advanced, is due and payable in full on the term loan maturity date. The 2017 Secured Loan Agreement has a term of five years and matures on January 1, 2022.

At the Company's option, the Company may prepay all, but not less than all, of the term loans advanced by Oxford under the 2017 Secured Loan Agreement, subject to a prepayment fee and an amount equal to the sum of all outstanding principal of the term loans plus accrued and unpaid interest thereon through the prepayment date, a final payment, plus all other amounts that are due and payable, including Oxford's expenses and interest at the default rate with respect to any past due amounts.

The Company intends to refinance the 2017 Secured Loan Agreement before the interest only period ends and the principal repayments begin in January 2020. The Company may not be able to refinance or obtain additional financing on terms favorable to the Company, 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 the Company's ability to take specific actions, such as incurring additional debt or making capital expenditures. If the Company is unable to refinance the 2017 Secured Loan Agreement before the interest only period ends or shortly thereafter, then the Company will be required to make principal repayments beginning in January 2020 which will require the Company to raise additional capital through the sale of equity and the ownership interest of our stockholders will be diluted.

The 2017 Secured Loan Agreement 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 Secured Loan Agreement, including foreclosure against assets securing the 2017 Secured Loan Agreement, including the Company's cash. These events of default include, among other things, the Company's failure to pay any amounts due under the 2017 Secured Loan Agreement, a breach of covenants under the 2017 Secured Loan Agreement, including, among other customary debt covenants, achieving certain revenue levels and limiting the amount of cash and cash equivalents held by the Company's foreign subsidiaries, 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 the Company 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, 2018, the Company was not in breach of covenants under the Amended 2017 Secured Loan Agreement.

Note L—Related Party Transactions

Vertegen

In April 2007, the Company entered into a license agreement with Vertegen, Inc., or Vertegen, which was amended in May 2015 (the “Vertegen Agreement”). Vertegen is an entity that is wholly owned by Dr. Lang, the Company’s former Chief Executive Officer. Under the Vertegen Agreement, Vertegen granted the Company an exclusive, worldwide license under specified Vertegen patent rights and related technology to make, use and sell

products and services in the fields of diagnosis and treatment of articular disorders and disorders of the human spine. The Company may sublicense the rights licensed to it by Vertegen. The Company is required to use commercially reasonable efforts, at its sole expense, to prosecute the patent applications licensed to the Company by Vertegen. Pursuant to the Vertegen Agreement, the Company is required to pay Vertegen a 6% royalty on net sales of products covered by the patents licensed to the Company by Vertegen, the subject matter of which is directed primarily to spinal implants, and any proceeds from the Company enforcing the patent rights licensed to the Company by Vertegen. Such 6% royalty rate will be reduced to 3% in the United States during the five-year period following the expiration of the last-to-expire applicable patent in the United States and in the rest of the world during the five-year period following the expiration of the last-to-expire patent anywhere in the world. The Company has not sold any products subject to this agreement and has paid no royalties under this agreement. The Company has cumulatively paid approximately $175,000, $150,000, and $150,000 in expenses in connection with the filing and prosecution of the patent applications licensed to the Company by Vertegen for the years ended December 31, 2018, 2017, and 2016 respectively.

The Vertegen Agreement may be terminated by the Company at any time by providing notice to Vertegen. In addition, Vertegen may terminate the Vertegen Agreement in its entirety if the Company is in material breach of the agreement, and the Company fails to cure such breach during a specified period.

Revenue share agreements

As described in "Note J—Commitments and Contingencies", the Company is a party to certain agreements with advisors to participate as a member of the Company’s scientific advisory board. In September 2011, the Company entered into an amended and restated revenue share agreement with Philipp Lang, M.D., former Chief Executive Officer and director, which amended and restated a similar agreement entered into in 2008 when Dr. Lang stepped down as chair of the Company’s scientific advisory board and became the Company’s Chief Executive Officer. This agreement provides that the Company will pay Dr. Lang a specified percentage of our net revenue, ranging from 0.875% to 1.33%, with respect to all of our current and planned products, including the Company’s iUni, iDuo, iTotal CR, iTotal PS, and Conformis Hip System products, as well as certain other knee, hip and shoulder replacement products and related instrumentation the Company may develop in the future. The specific percentage is determined by reference to product classifications set forth in the agreement and is tiered based on the level of net revenue collected by the Company on such product sales. The Company’s payment obligations expire on a product-by-product basis on the last to expire of the Company’s patents on which Dr. Lang is a named inventor that include a claim covering the applicable product. These payment obligations survived the termination of Dr. Lang’s employment with the Company. We have raised concerns with Dr. Lang relating to this revenue share agreement and have been seeking to enter into discussions with Dr. Lang concerning the scope of this agreement. In October of 2018, the Company requested that Dr. Lang provide consulting services as permitted under Dr. Lang’s revenue share agreement. However, he failed to respond to such request and, as a result, beginning in the fourth quarter of 2018, the revenue share percentage rate owed to Dr. Lang has been reduced by 50% within the scope of his agreement. The Company incurred revenue share expense for Dr. Lang of $0.7 million, $1.0 million and $1.0 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Note M—Stockholders’ Equity

Common stock

Common stockholders are entitled to dividends as and when declared by the board of directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date.

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Summary of common stock activity was as follows:

	Shares
Outstanding December 31, 2016	43,399,547
Issuance of common stock - option & warrant exercises	535,734
Issuance of restricted common stock	1,195,196
Issuance of common stock - ATM offering	228,946
Issuance of common stock - BPM acquisition	169,096
Outstanding December 31, 2017	45,528,519
Issuance of common stock - option exercises	80,000
Issuance of restricted common stock	1,516,295
Issuance of common stock - ATM offering	556,334
Issuance of common stock - LPC offering	2,276,398
Issuance of common stock - 2018 offering	15,333,333
Outstanding December 31, 2018	65,290,879

Preferred stock

The Company’s Restated Certificate of Incorporation authorizes the Company to issue 5,000,000 shares of preferred stock, $0.00001 par value, all of which is undesignated. No shares were issued and outstanding at December 31, 2018 and December 31, 2017.

Demand registration rights

In conjunction with the IPO, the Company entered into an Amended and Restated Information and Registration Rights Agreement effective June 29, 2015 (the “Registration Rights Agreement”), which provided, among other things, registration rights to certain investors that had held the Company's preferred stock prior to the IPO. Subject to specified limitations set forth in a registration rights agreement, at any time, the holders of at least 25% of the then outstanding registrable shares may at any time demand in writing that the Company register all or a portion of the registrable shares under the Securities Act on a Form other than Form S-3 for an offering of at least 20% of the then outstanding registrable shares or a lesser percentage of the then outstanding registrable shares provided that it is reasonably anticipated that the aggregate offering price would exceed $20 million. The Company is not obligated to file a registration statement pursuant to these rights on more than two occasions. Additionally, after such time as the Company became eligible to use Form S-3, subject to specified limitations set forth in the registration rights agreement, the holders of at least 25% of the then outstanding registrable shares became able to at any time demand in writing that the Company register all or a portion of the registrable shares under the Securities Act on Form S-3 for an offering of at least 25% of the then outstanding registrable shares having an anticipated aggregate offering price to the public, net of selling expenses, of at least $5 million (a “Resale Registration Statement”). The Company is not obligated to effect a registration pursuant to a Resale Registration Statement on more than one occasion.

Incidental registration rights

If, the Company proposes to file a registration statement in connection with a public offering of its common stock, subject to certain exceptions, the holders of registrable shares are entitled to notice of registration and, subject to specified exceptions, including market conditions, the Company will be required, upon the holder’s request, to register their then held registrable shares.

Warrants

The Company also issued warrants to certain investors and consultants to purchase shares of the Company’s preferred stock and common stock. Based on the Company’s assessment of the warrants granted in 2013 and 2014 relative to ASC 480, Distinguishing Liabilities from Equity, the warrants are classified as equity. No warrants were issued in the

years ended December 31, 2018 and 2017. All warrants were exercisable immediately upon issuance.

Common stock warrants

The Company also issued warrants to certain investors and consultants to purchase shares of common stock. Warrants to purchase 28,926 shares of common stock were outstanding as of December 31, 2018 and December 31, 2017. Outstanding warrants are currently exercisable with varying exercise expiration dates from 2020 through 2024.

Summary of common stock warrant activity was as follows:

	Number of Warrants	Weighted Average Exercise Price Per Share	Number of Warrants Exercisable	Weighted Average Price Per Share	Weighted Average Contractual Life
Outstanding December 31, 2016	171,783	$ 7.47	171,783	$ 7.47	1.62
Cancelled/expired	(142,857)	7.00	(142,857)	7.00	—
Outstanding December 31, 2017	28,926	$ 9.80	28,926	$ 9.80	5.66
Outstanding December 31, 2018	28,926	$ 9.80	28,926	$ 9.80	4.66

Stock option plans

In June 2004, the Company authorized the adoption of the 2004 Stock Option and Incentive Plan (the “2004 Plan”). Under the 2004 Plan, options were granted to persons who were, at the time of grant, employees, officers, or directors of, or consultants or advisors to, the Company. The 2004 Plan provided for the granting of non-statutory options, incentive options, stock bonuses, and rights to acquire restricted stock.

The option price at the date of grant was determined by the Board of Directors and, in the case of incentive options, could not be less than the fair market value of the common stock at the date of grant, as determined by the Board of Directors. Options granted under the 2004 Plan generally vest over a period of four years and are set to expire ten years from the date of grant. In February 2011, the Company terminated the 2004 Plan and all options outstanding under it were transferred to the 2011 Stock Option/Stock Issuance Plan (the “2011 Plan”).

In February 2011, the Company authorized the adoption of the 2011 Plan. The 2011 Plan is divided into two separate equity programs, Option Grant Program and Stock Issuance Program. Per the 2011 Plan, options can be granted to persons who are, at the time, employees, officers, or directors of, or consultants or advisors to, the Company. The 2011 Plan provides for the granting of non-statutory options, incentive options and common stock. The price at the date of grant is determined by the Board of Directors and, in the case of incentive options and common stock, cannot be less than the fair market value of the common stock at the date of grant, as determined by the Board of Directors. Options granted under the 2011 Plan generally vest over a period of four years and expire ten years from the date of grant.

In June 2015, the Company terminated the 2011 Plan and all options outstanding under it were transferred to the 2015 Stock Incentive Plan (the “2015 Plan”).

The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares of our common stock that will be reserved for issuance under the 2015 Plan is the sum of: (1) 2,000,000; plus (2) the number of shares equal to the sum of the number of shares of our common stock then available for issuance under the 2011 Plan and the number of shares of our common stock subject to outstanding awards under the 2011 Plan or under the 2004 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2016 and continuing until, and including, the fiscal year ending December 31, 2025, equal to the least of (a) 3,000,000 shares of our common stock, (b) 3% of the number of shares of

our common stock outstanding on the first day of such fiscal year and (c) an amount determined by the Board. Our employees, officers, directors, consultants and advisors will be eligible to receive awards under the 2015 Plan. Incentive stock options, however, may only be granted to our employees. Options and restricted stock awards granted under the 2015 Plan generally vest over a period of four years and expire ten years from the date of grant. As of December 31, 2018, 1,572,828 shares of common stock were available for future issuance under the 2015 Plan.

Activity under all stock option plans was as follows:

	Number of Options	Weighted Average Exercise Price per Share	Aggregate Intrinsic Value (In Thousands)
Outstanding December 31, 2015	5,248,329	$ 5.56	$ 61,741
Granted	179,178	8.78	
Exercised	(1,467,692)	2.78	$ 8,219
Expired	(81,251)	9.70	
Cancelled/Forfeited	(88,524)	9.93	
Outstanding December 31, 2016	3,790,040	$ 6.60	$ 8,547
Granted	963,350	4.95	
Exercised	(535,734)	3.94	1,688
Expired	(466,210)	7.17	
Cancelled/Forfeited	(123,451)	6.54	
Outstanding December 31, 2017	3,627,995	$ 6.48	$ 96
Granted	165,219	1.36	
Exercised	(80,000)	1.40	1,688
Expired	(589,051)	5.91	
Cancelled/Forfeited	(247,964)	5.10	
Outstanding December 31, 2018	2,876,199	$ 6.57	$ —
Total vested and exercisable	2,320,263	$ 7.05	$ —

The total fair value of stock options that vested during the year ended December 31, 2018 was $1.1 million. The weighted average remaining contractual term for the total stock options outstanding was 4.68 years at December 31, 2018. The weighted average remaining contractual term for the total stock options vested and exercisable was 3.75 years at December 31, 2018.

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

	Number of Shares	Weighted Average Fair Value
Unvested December 31, 2015	174,530	$ 22.31
Granted	873,589	8.61
Vested	(66,839)	17.72
Forfeited	(69,570)	11.83
Unvested December 31, 2016	911,710	10.32
Granted	1,421,364	4.20
Vested	(767,785)	7.11
Forfeited	(226,168)	7.36
Unvested December 31, 2017	1,339,121	$ 6.06
Granted	2,485,565	1.34
Vested	(382,044)	6.49
Forfeited	(969,270)	3.00
Unvested December 31, 2018	2,473,372	$ 2.45

The total fair value of restricted common stock awards that vested during the year ended December 31, 2018 was $2.5 million.

Stock-based compensation

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options. The determination of the fair value of stock-based payment awards on the date of grant using a pricing model is affected by the value of the Company's common stock as well as assumptions regarding a number of complex and subjective variables. As the valuations included unobservable inputs that were primarily based on the Company's own assumptions, the inputs were considered level 3 inputs within the fair value hierarchy.

The weighted average fair value of options granted was $0.73 for the year ended December 31, 2018, $2.49 for the year ended December 31, 2017 and $4.46 for the year ended December 31, 2016.

The fair value of options at date of grant was estimated using the Black-Scholes option pricing model, based on the following assumptions:

	Years Ended December 31,		
	2018	2017	2016
Risk-free interest rate	2.75% - 2.90%	2.10% - 2.30%	1.98%
Expected term (in years)	6.25	6.02 - 6.25	6.25
Dividend yield	—%	—%	—%
Expected volatility	53.00% - 56.00%	51.00% - 53.00%	51.00%

Risk-free interest rate. The risk-free interest rate is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

Expected term. The expected term of stock options represents the period the stock options are expected to remain outstanding and is based on the “SEC Shortcut Approach” as defined in “Share-Based Payment” (SAB 107) ASC 718-10-S99, “Compensation—Stock Compensation—Overall—SEC Materials,” which is the midpoint between the vesting dat and the end of the contractual term. With certain stock option grants, the exercise price may exceed the fair value of the common stock. In these instances, the Company adjusts the expected term accordingly.

Dividend yield. The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and, therefore, used an expected dividend yield of zero in the valuation model.

Expected volatility. Expected volatility measures the amount that a stock price has fluctuated or is expected to fluctuate during a period. The Company does not have sufficient history of market prices of its common stock as it is a newly public company. Therefore, the Company estimates volatility using historical volatilities of similar public entities.

Forfeitures. Effective January 1, 2017, the Company elected to change its accounting policy to recognize forfeitures as they occur in accordance with ASU 2016-09, "Compensation - Stock Compensation". Prior to this election, the Company recognized share-based compensation net of estimated forfeitures over the vesting period of the respective grant.

Stock-based compensation expense was $3.9 million, $6.0 million and $5.3 million for the years ended December 31, 2018, 2017 and 2016, respectively. Stock-based compensation expense was recognized ratably over the period with forfeitures accounted for in the period in which they occurred. To date, the amount of stock-based compensation capitalized as part of inventory was not material. The following is a summary of stock-based compensation expense (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Cost of revenue	$333	$441	$333
Sales and marketing	501	919	1,197
Research and development	1,029	1,920	1,466
General and administrative	2,023	2,768	2,328
	$3,886	$6,048	$5,324

At December 31, 2018, the Company had $1.2 million of total unrecognized compensation expense for options that will be recognized over a weighted average period of 2.51 years. At December 31, 2018, the Company had $4.5 million of total unrecognized compensation expense for restricted awards recognized over a weighted average period of 2.65 years.

Note N—Income Taxes

The Company files U.S. federal and state tax returns as well as foreign income tax returns. The Company has accumulated significant losses since its inception in 2004. For financial reporting purposes, loss before income taxes for the years ended December 31, 2018, 2017 and 2016 includes the following components (in thousands):

	Years ended December 31,		
	2018	2017	2016
Loss before income taxes:			
U.S.	$(38,219)	$(53,274)	$(51,576)
Non U.S.	(5,085)	(144)	(5,949)
	$(43,304)	$(53,418)	$(57,525)

Significant components of the provision for income taxes for the years ended December 31, 2018, 2017 and 2016 were as follows (in thousands):

	Years ended December 31,		
	2018	2017	2016
Current:			
Federal	$—	$—	$—
State	—	—	—
Foreign	98	125	63
	98	125	63
Deferred:			
Federal	(37)	37	—
State	—	—	—
Foreign	—	—	—
	(37)	37	—
Total	$61	$162	$63

The Company accounts for income taxes under FASB ASC 740 Accounting for Income Taxes. Deferred tax assets and liabilities are determined based upon differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A reconciliation of the income tax benefit at the statutory federal income tax rate as reflected in the financial statements was as follows:

	Years ended December 31,		
	2018	2017	2016
Tax at U.S. statutory rate	(21.00)%	(34.00)%	(34.00)%
State taxes, net of federal benefits	(3.48)	(3.12)	(2.70)
Permanent items	1.03	1.96	0.42
Tax credit	(2.27)	(1.35)	(1.06)
Change in valuation allowance	(198.36)	(54.85)	33.95
Foreign rate differential	(1.21)	(0.17)	1.04
Rate change	(0.09)	90.78	(0.06)
Uncertain tax positions	0.22	0.41	2.06
NQ Stock option expirations & forfeitures	1.29	—	—
Federal NOL limitation	196.32	—	—
State NOL limitation	25.72	—	—
Deferred revenue - ASC 606 implementation adjustment	2.49	—	—
Other	(0.52)	0.64	0.46
	0.14 %	0.30 %	0.11 %

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes

Significant components of the Company’s deferred tax assets (liabilities) consisted of the following (in thousands):

	Years ended December 31,	
	2018	2017
Deferred tax assets:		
Federal and state net operating loss carryforwards	$644	$90,437
Foreign net operating loss carryforwards	2,687	2,561
Accrued expenses	99	157
Credits	7,038	6,055
Deferred revenue	—	1,068
Intangibles	1,350	—
Stock compensation expense	1,917	1,805
Other	3,151	2,111
Total deferred tax assets	16,886	104,194
Valuation allowance	(16,064)	(103,430)
Net deferred tax assets	822	764
Deferred tax liabilities:		
Fixed assets	(822)	(664)
Intangibles	—	(134)
Other	—	(3)
Net deferred tax liabilities	(822)	(801)
Net deferred tax liabilities	$—	$(37)

A valuation allowance is required to reduce the deferred tax assets reported if, based on weight of evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all of the evidence, both positive and negative, the Company determined that a $16.1 million valuation allowance at December 31, 2018 was necessary to reduce the deferred tax assets to the amount that will more likely than not be realized. The change in the valuation allowance for the current year was $87.4 million.

The Company provided a valuation allowance for the full amount of its net deferred tax asset for all periods because realization of any future tax benefit cannot be sufficiently assured as the Company does not expect income in the near term.

At December 31, 2018, the Company had approximately $403.6 million of federal net operating loss carryforwards and approximately $219.2 million of state net operating loss carryforwards that if not utilized, will begin to expire in 2020 for federal tax purposes and continue to expire at various dates starting for state tax purposes. The utilization of such net operating loss carryforwards and realization of tax benefits in future years depends predominantly upon having taxable income. The limitations under Section 382 for Federal and State are $345.8 million and $11.1 million as of December 31, 2018. The limitations may reduce the amount of federal and state NOLs and credits of $403.6 million and $219.2 million, respectively, that can be utilized to offset future taxable income and tax.

Utilization of the NOLs and credits may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 and Section 383 of the Code. In general, an “ownership change” as defined by Section 382 of the Code results from a transaction or series of transactions over a three year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders. The Company underwent an ownership change in January 2018 and as a result the Company is subject to an annual limitation of approximately $1.4 million.

The Company also had foreign net operating losses of approximately $30.5 million as of December 31, 2018, which may be available to offset future income recognized in the Federal Republic of Germany and the United Kingdom. The net operating losses in Germany and the United Kingdom have indefinite carryforward periods.

The Company has adopted the accounting guidance related to uncertainty in income taxes. The total liability for unrecognized income tax benefits was approximately $6.8 million as of December 31, 2018, $5.1 million as of December 31, 2017 and $4.9 million of December 31, 2016. Of the total liability at December 31, 2018 and

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2017, $6.4 million and $4.9 million, respectively, were netted against deferred tax assets. The Company recognizes interest accrued and penalties, if applicable, related to unrecognized tax benefits in income tax expense. The Company does not expect any significant changes in the next 12 months.

The reconciliation below summarizes the Company's unrecognized tax benefits for the respective periods. These amounts primarily relate to transactions between the Company and its foreign subsidiaries, including accrued interest.

	Years ended December 31,		
	2018	2017	2016
Unrecognized tax benefits beginning of year	$5,136	$4,918	$3,730
Gross change for current year positions	1,628	219	1,187
Unrecognized tax benefits end of the year	$6,764	$5,136	$4,918

As of December 31, 2018, the Company was open to examination in the U.S. federal and certain state jurisdictions for all of the Company’s tax years since the net operating losses may potentially be utilized in future years to reduce taxable income. The Company has been audited in Germany through 2015. The net operating loss carryforward from periods prior to 2015 may be utilized against taxable income in future periods and the net operating loss carryforward can be challenged at that time.

At December 31, 2018, foreign earnings, which were not significant, have been retained indefinitely by foreign subsidiary companies for reinvestment; therefore, no provision has been made for income taxes that would be payable upon the distribution of such earnings, and it would not be practicable to determine the amount of the related unrecognized deferred income tax liability. Upon repatriation of those earnings, in the form of dividends or otherwise, the Company could be subject to immaterial withholding taxes payable to the various foreign countries.

ASU No. 2016-09, "Compensation - Stock Compensation", was issued and adopted in January 2017. ASU 2016-09 eliminates APIC pools and requires excess tax benefits and tax deficiencies to be recorded in the income statement when the awards vest or are settled. In addition, modified retrospective adoption of ASU 2016-09 eliminates the requirement that excess tax benefits be realized (i.e., through a reduction in income taxes payable) before the Company can recognize them and therefore, it has accounted for a cumulative-effect adjustment of $7.7 million during the twelve months ended December 31, 2017 to record excess tax benefits. Since the Company has a full valuation allowance on all deferred taxes, this has no impact on retained earnings or the tax position of the Company.

On December 22, 2017, H.R.1., known as the Tax Cuts and Jobs Act, was signed into law. The new law did not have a significant impact on the Company’s consolidated financial statements for the year ended December 31, 2017. However, the reduction of the U.S. federal corporate tax rate from 35% to 21% resulted in increases to the amounts reflected in “(Benefit from) provision for income taxes attributable to valuation allowances” and “Rate change” in the Company’s tax reconciliation table above for the year ended December 31, 2017 compared to the year ended December 31, 2016. The change in the U.S. federal corporate tax rate, which was effective January 1, 2018, is also reflected in the Company’s deferred tax table above.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118's ("SAB 118") to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of H.R.1. The Company recognized the provisional tax impacts related to deemed repatriated earnings and the revaluation of deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. The Company did not record any adjustments in the year ended December 31, 2018 to these provisional amounts that were material to its financial statements. As of December 31, 2018, the Company’s accounting treatment is complete.

Note O—Segment and Geographic Data

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The Company operates as one reportable segment as described in "Note B—Summary of Significant Accounting Policies" to the Consolidated Financial Statements. The countries in which the Company has local revenue generating operations have been combined into the following geographic areas: the United States (including Puerto Rico), Germany and the rest of the world, which consists of Europe predominately (including the United Kingdom) and other foreign countries. Sales are attributable to a geographic area based upon the customer's country of domicile. Net property, plant and equipment are based upon physical location of the assets.

Geographic information consisted of the following (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Product Revenue			
United States	$68,057	$64,307	$62,366
Germany	9,007	11,296	14,701
Rest of World	1,563	1,497	1,854
	$78,627	$77,100	$78,921

	December 31,	
	2018	2017
Property and equipment, net		
United States	$14,367	$16,424
Rest of World	72	90
	$14,439	$16,514

Note P —Employee Savings Plan

We have established an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code. The plan allows participating employees to deposit into tax deferred investment accounts up to 80% of eligible earnings, subject to annual limits. We make contributions to the plan in an amount equal to 50% of elective deferrals on up to 5% of the participant's eligible earnings. We contributed approximately $561,000, $457,000 and $478,000 to the plan during the years ended December 31, 2018, 2017 and 2016, respectively.

Note Q —Selected Quarterly Financial Information (Unaudited)

	Three Months Ended			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
Total revenue	$22,049	$ 28,984	$19,100	$19,656
Gross profit	10,868	19,719	9,111	8,787
Net loss	(9,870)	(7,437)	(14,057)	(12,001)
Net loss per share - basic and diluted	$(0.16)	$ (0.12)	$(0.24)	$(0.22)

	Three Months Ended			
	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
Total revenue	$20,751	$ 18,425	$18,484	$20,455
Gross profit	8,757	7,314	6,248	6,494
Net loss	(11,858)	(12,472)	(12,090)	(17,160)
Net loss per share - basic and diluted	$(0.27)	$ (0.29)	$(0.28)	$(0.4)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2018, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal controls over financial reporting include those policies and procedures that:

(1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with the authorization of our management; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of the Company's internal controls and procedures over financial reporting as of December 31, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of these controls.

Based on this assessment, management has concluded that as of December 31, 2018, our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

Attestation Report of the Independent Public Accounting Firm

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to applicable rules of the SEC that permit the Company to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the year ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On March 8, 2019, we entered into a third amendment to the amended and restated employment agreement with Mark Augusti, our Chief Executive Officer, (the “Augusti Amendment”). The Augusti Amendment provides that, as of March 31, 2019, the currently provided reimbursement of up to $25,000 per calendar quarter for Residency and Travel Expenses (as defined in the Augusti Amendment) will cease. In recognition that the reimbursement of Residency and Travel Expenses is and has been taxable compensation to Mr. Augusti, under the Augusti Amendment, we have agreed to pay Mr. Augusti $100,000 as an amount intended to cover taxes paid and to be paid by him resulting from receipt of Residency and Travel Expense payments from August 2, 2017 through March 31, 2019. Beginning April 1, 2019, the Augusti Amendment provides that we will pay Mr. Augusti a fixed amount of $41,666.50 per quarter with the intention that he will receive a net amount of approximately $25,000 on an after-tax basis to use for his travel and residency expenses, until the earlier of: (i) the establishment of Mr. Augusti’s principal residence in Massachusetts or (ii) a determination by the Board of Directors in its sole discretion that the payment of such Residency and Travel Expenses is no longer required.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Directors and Executive Officers

The other information required by this item will be set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Compliance with Section 16(a) of the Exchange Act

The information required by this item will be set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Code of Ethics

We have adopted a written code of business conduct and ethics that applies to our directors and officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) as well as our other employees. A copy of our code of business conduct and ethics is available on our website www.conformis.com, under the heading "Investors—Corporate Governance". We intend to post on our website all disclosures that are required by applicable law, the rules of the Securities and Exchange Commission or the NASDAQ Global Select Market concerning any amendment to, or waiver of, our code of business conduct and ethics.

Director Nominees

The information required by this item will be set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Audit Committee

We have separately designated a standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Additional information regarding the Audit Committee that is required by this item will be set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Audit Committee Financial Expert

Our board of directors has determined that Bradley Langdale is the “audit committee financial expert” as defined by Item 407(d)(5) of Regulation S-K of the Exchange Act and is “independent” under the rules of the NASDAQ Global Market.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Annual Report on Form 10-K:

1. Consolidated Financial Statement

For a list of consolidated financial statements included herein, see Index to the Consolidated Financial Statements on page 84 of this Annual Report on Form 10-K, incorporated into this item by reference.

2. Financial Statement Schedules:

No financial statement schedules have been submitted because they are not required or are not applicable because the information the required is included in the consolidated financial statements or the notes thereto.

3. Exhibits

The exhibits filed as part of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page, which Exhibit Index is incorporated herein by reference.

ITEM 16. FORM 10-K SUMMARY

We may voluntarily include a summary of information required by Form 10-K under this Item 16. We have elected not to include such summary information.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
1.1	Underwriting Agreement, dated as of January 25, 2018, by and among the Registrant and Cowen and Company LLC and Canaccord Genuity, Inc. as representatives of the several underwriters listed on Schedule 1 thereto (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on January 25, 2018)
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-3747) filed on July 8, 2015)
3.2	Articles of Amendment to Restated Certificate of Incorporation of Registrant dated May 1, 2018 (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37474) filed on May 4, 2018)
3.3	Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K (File No. 001-3747) filed on July 8, 2015)
4.1	Specimen certificate evidencing shares of common stock (incorporated by reference to Exhibit 4.1 to the Registrant's registration statement on Form S-1/A (File No. 333-204384) filed on June 18, 2015)
10.1	Amended and Restated Information and Registration Rights Agreement, dated as of June 29, 2015, among the Registrant and the other parties thereto (incorporated by reference to Exhibit 10.1 to the Registrant's registration statement on Form S-1/A (File No. 333-204384) filed on June 29, 2015)
10.2+	2004 Stock Option Plan (incorporated by reference to Exhibit 10.2 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.3+	Form of Incentive Stock Option Agreement under 2004 Stock Option Plan (incorporated by reference to Exhibit 10.3 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.4+	Form of Nonqualified Stock Option Agreement under 2004 Stock Option Plan (incorporated by reference to Exhibit 10.4 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.5+	Form of Stock Purchase Agreement for Incentive Stock Option Agreement under 2004 Stock Option Plan (incorporated by reference to Exhibit 10.5 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.6+	Form of Stock Purchase Agreement for Nonqualified Stock Option Agreement under 2004 Stock Option Plan (incorporated by reference to Exhibit 10.6 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.7+	2011 Stock Option/Stock Issuance Plan (incorporated by reference to Exhibit 10.7 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.8+	Form of Notice of Grant of Incentive Stock Option under 2011 Stock Option/Stock Issuance Plan (incorporated by reference to Exhibit 10.8 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.9+	Form of Notice of Grant of Nonstatutory Stock Option under 2011 Stock Option/Stock Issuance Plan (incorporated by reference to Exhibit 10.9 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.10+	Form of Stock Purchase Agreement under 2011 Stock Option/Stock Issuance Plan (incorporated by reference to Exhibit 10.10 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.11+	2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.11 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)

10.12+	Form of Incentive Stock Option Agreement under 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.12 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.13+	Form of Nonstatutory Stock Option Agreement under 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.13 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)

10.14+	Form of Restricted Stock Agreement under 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.34 to the Registrant's registration statement on Form S-1/A (File No. 333-204384) filed on June 18, 2015)
10.15+	Amended and Restated Employment Agreement, dated as of May 21, 2015, between the Registrant and Paul Weiner, together with the Employee Confidential Information, Inventions and Non-Competition Agreement, dated as of May 21, 2015, between the Registrant and Paul Weiner (incorporated by reference to Exhibit 10.15 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.16+	Amended and Restated Revenue Sharing Agreement, dated as of September 2, 2011, between the Registrant and Philipp Lang (incorporated by reference to Exhibit 10.18 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.17+	Form of Director and Officer Indemnification Agreement (incorporated by reference to Exhibit 10.20 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.18	Lease Agreement, dated as of August 20, 2014, between the Registrant and Wakefield Investments, Inc. (incorporated by reference to Exhibit 10.23 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.19	Sublease, dated as of May 30, 2012, between the Registrant and Reveal Imaging Technologies, Inc. (incorporated by reference to Exhibit 10.24 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.20	First Amendment to Lease dated July 25, 2016 between Wakefield Investments, Inc. and Registrant for 600 Research Drive, Wilmington, Massachusetts (incorporated herein by reference to Exhibit 10.26 of the Registrant's Annual Report on Form 10-K for the period ended December 31, 2016, filed with the Securities and Exchange Commission on March 8, 2017, File No. 001-37474)
10.21	Lease dated September 19, 2016 between Technology Park I Limited Partnership and Registrant for 600 Technology Park Drive, Billerica, Massachusetts (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2016, filed with the Securities and Exchange Commission on November 10, 2016, File No. 001-37474)
10.22	License Agreement, effective as of April 10, 2007, between the Registrant and Vertegen, Inc., as amended by First Amendment to License Agreement, dated as of May 20, 2015, between the Registrant and Vertegen, Inc. (incorporated by reference to Exhibit 10.26 to the Registrant's registration statement on Form S-1/A (File No. 333-204384) filed on June 11, 2015)
10.23	Sponsor Designee Recommendation Agreement, dated as of May 21, 2015, between the Registrant and Procific (incorporated by reference to Exhibit 10.29 to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
10.24†	License Agreement, dated as of April 13, 2015, between the Registrant and MicroPort Orthopedics Inc. (incorporated by reference to Exhibit 10.32 to the Registrant's registration statement on Form S-1/A (File No. 333-204384) filed on June 11, 2015)
10.25	License Agreement, dated as of April 13, 2015, between the Registrant and each of Wright Medical Group, Inc. and Wright Medical Technology, Inc. (incorporated by reference to Exhibit 10.33 to the Registrant's registration statement on Form S-1/A (File No. 333-204384) filed on June 11, 2015)
10.26	Form of Retention Agreements of Certain Officers (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2016, filed with the Securities and Exchange Commission on August 11, 2016, File No. 001-37474)
10.27	Summary of Compensatory Arrangements of Certain Officers (incorporated by reference to the Registrant's Form 8-K filed on February 9, 2016, File No. 001-37474)
10.28+	Employment Agreement, dated October 19, 2016, by and between the Registrant and Mark A. Augusti, as amended and restated effective December 2, 2016 (incorporated herein by reference to Exhibit 10.34 of the Registrant's Annual Report on Form 10-K for the period ended December 31, 2016, filed with the Securities and Exchange Commission on March 8, 2017, File No. 001-37474)

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10.29	Distribution Agreement, dated May 10, 2017, by and between ConforMIS, Inc. and Canaccord Genuity Inc. (incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2017, filed with the Securities and Exchange Commission on May 10, 2017, File No. 001-37474)
10.30	Loan and Security Agreement, dated January 6, 2017, by and between Conformis, Inc. and Oxford Finance, LLC (incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on January 9, 2017)
10.31	First Amendment to Loan and Security Agreement, dated March 9, 2017, by and among Registrant and Oxford Finance LLC (incorporated herein by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-37474) filed on May 10, 2017)
10.32	Agreement Regarding Sublease dated April 13, 2017 between CCC Investors, LLC and Registrant for 28 Crosby Drive, Bedford, Massachusetts incorporated herein by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-37474) filed on May 10, 2017)
10.33	Second Amendment to Loan and Security Agreement, dated June 30, 2017, by and among Registrant and Oxford Finance LLC (incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on July 3, 2017)
10.34†	Asset Purchase Agreement dated August 9, 2017, by and between Conformis, Inc. and Broad Peak Manufacturing, LLC (incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-37474) filed on November 9, 2017)
10.35+	Amendment to Employment Agreement dated September 14, 2017, by and between Conformis, Inc. and Mark Augusti, its President and Chief Executive Officer (incorporated herein by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-37474) filed on November 9, 2017)
10.36	Third Amendment to Loan and Security Agreement, dated December 18, 2017, by and among Registrant and Oxford Finance LLC (incorporated herein by reference to Exhibit 10.40 of the Registrant's Annual Report on Form 10-K (File No. 001-37474) filed on March 9, 2018)
10.37+	Second Amendment to the Amended and Restated Employment Agreement dated March 9, 2018, by and between Conformis, Inc. and Paul S. Weiner (incorporated herein by reference to Exhibit 10.41 of the Registrant's Annual Report on Form 10-K (File No. 001-37474) filed on March 9, 2018)
10.38+	Employment Agreement dated March 14, 2018, by and between Conformis, Inc. and Patricia A. Davis, its Chief Legal Officer, General Counsel and Corporate Secretary (incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-37474) filed on May 4, 2018)
10.39+	First Amendment to Employment Agreement dated May 3, 2018, by and between Conformis, Inc. and Patricia A. Davis, its Chief Legal Officer, General Counsel and Corporate Secretary (incorporated herein by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-37474) filed on May 4, 2018)
10.40+	Third Amendment to Employment Agreement dated May 3, 2018, by and between Conformis, Inc. and Paul S. Weiner, its Chief Financial Officer (incorporated herein by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-37474) filed on May 4, 2018)
10.41+	Second Amendment to Amended and Restated Employment Agreement dated July 31, 2018, by and between Conformis, Inc. and Mark Augusti, its Chief Executive Officer (incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-37474) filed on August 2, 2018)
10.42	Fourth Amendment to Loan and Security Agreement, dated July 31, 2018, by and among Registrant and Oxford Finance LLC (incorporated herein by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-37474) filed on August 2, 2018)
10.43†	Settlement and License Agreement dated September 14, 2018 between Conformis, Inc. and Smith & Nephew, Inc. (incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File

	No. 001-37474) filed on November 5, 2018)
10.44	Fifth Amendment to Loan and Security Agreement, dated December 13, 2018, by and among Registrant and Oxford Finance LLC (incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on December 14, 2018)

10.45	Registration Rights Agreement dated December 17, 2018 by and between Conformis, Inc. and Lincoln Park Capital Fund, LLC (incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on December 18, 2018)
10.46+*	Amendment to Employment Agreement dated March 8, 2019, by and between Conformis, Inc. and March Augusti, its President and Chief Executive Officer
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 10.21. to the Registrant's registration statement on Form S-1 (File No. 333-204384) filed on May 22, 2015)
23.1*	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Database
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

* Filed herewith.

† Confidential treatment has been granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

+ Indicates management contract or plan.

This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: March 12, 2019

CONFORMIS, INC.
By: /s/Mark A. Augusti
Mark A. Augusti
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/Mark A. Augusti Mark A. Augusti	President and Chief Executive Officer (Principal Executive Officer) and Director	March 12, 2019
/s/Paul Weiner Paul Weiner	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2019
/s/Kenneth Fallon III Kenneth Fallon III	Chairman of the Board of Directors	March 12, 2019
/s/Philip W. Johnston Philip W. Johnston	Director	March 12, 2019
/s/Carrie Bienkowski Carrie Bienkowski	Director	March 12, 2019
/s/Bradley Langdale Bradley Langdale	Director	March 12, 2019
/s/Richard Meelia Richard Meelia	Director	March 12, 2019
/s/Michael Milligan Michael Milligan	Director	March 12, 2019