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, 2019

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 ☑

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 ☑

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 ☑ 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 ☑ 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 ☑

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 $233,752,261. As of February 28, 2020 there were 71,558,324 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, 2019. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

Conformis, Inc.

INDEX

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, our ability to raise additional funds, plans and objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

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

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

- our estimates regarding the potential market opportunity 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;
- the 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;
- our ability to achieve anticipated milestones under our collaborations;
- 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 obtain reimbursement or direct payment for our products and services;
- 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 or manufacturing 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.

Trademarks

Solely for convenience, our trademarks and trade names in this report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that we will not assert, to the fullest extent under applicable law, our rights thereto.

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 and instruments that are individually sized and shaped, which we refer to as personalized, individualized, or sometimes as customized, to fit each patient's unique anatomy. The worldwide market for joint replacement products is approximately $18.9 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 personalized knee implants and instruments designed to restore the natural shape of a patient's knee. We have sold a total of more than 110,000 knee implants worldwide, including more than 87,000 total knee implants and 22,000 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 of standard, or "off-the-shelf," implants that it was tested against. In 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. In July 2018, our first Conformis Hip Systems were implanted in a limited commercial launch. On November 11, 2019, we entered full commercial launch of the Conformis Hip System.

Our iFit technology platform comprises three key elements:

- *iFit Design*, our proprietary algorithms and computer software that we use to design personalized 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 personalized 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 personalized 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 and PS 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 personalized 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 personalized joint implants to restore each 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 personalized implants to follow the particular shape and contour of each 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

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-personalized). We provided financial support for this study and the author is a paid consultant of ours on other matters. In addition, in an October 2019 report from Beyond Compliance, results were presented summarizing five-year data from the England and Wales National Joint Registry demonstrating high survivorship in patients treated with the iTotal CR knee replacement implant, specifically the data showed a low cumulative percent revision of 1.8% for Conformis patients as compared with 2.2% 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 personalized 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 personalized 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; and
    - 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 January 31, 2020, we own or exclusively in-license a total of approximately 356 issued patents and pending patent applications that cover personalized implants and patient-specific instrumentation, or PSI, for all major joints and other elements of our iFit technology platform. Our intellectual property portfolio includes 158 issued United States patents, 127 patents issued in countries outside the United States, and 71 patent applications worldwide. See "Note J—Commitments and Contingencies—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 and related design software 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 and services 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, Argentina, Benelux, United Arab Emirates, Italy 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 2018 calendar year, which was published in May 2019 by Orthoworld Inc., or the 2018 Orthoworld Report, worldwide sales of joint replacement products, including replacements for knees, hips, shoulders, elbows, wrists, ankles and digits outside of trauma, exceeded $18.9 billion in 2018 and are expected to grow to approximately $22.9 billion by the end of 2023.

The 2018 Orthoworld Report estimated that worldwide sales of knee replacement products totaled approximately $9.1 billion and, according to Smart Track, the United States represented approximately 59% of total estimated worldwide sales of such products.

In 2018, according to the 2018 Orthoworld Report, worldwide sales of hip replacement products totaled approximately $7.6 billion. According to Smart Trak, the United States represented approximately 51% of the total estimated worldwide hip replacement sales. Smart Trak estimates that primary total hip replacement implants accounted for approximately 69% of revenue of the 2018 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, ankle and digits, may involve the replacement of the affected joint. According to the 2018 Orthoworld Report, the worldwide extremities joint replacement market was estimated at $2.3 billion in 2018.

The Conformis solution

No two joints are the same; accordingly, we believe no two implants should be the same. We believe our personalized joint replacement products, personalized planning services 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 personalized knee implants that are precisely sized and shaped to fit the unique three-dimensional curvatures of each patient's knee, as well as associated personalized, single-use patient-specific instrumentation, which we refer to as iJigs. We believe our proprietary iFit technology platform is applicable to all major joints.

iFit Image-to-Implant technology platform

Our iFit technology platform comprises three key elements:

- *iFit Design*, our proprietary algorithms, computer software and design services that we use to design personalized implants and their associated individualized iJigs based on a CT scan of the patient and to prepare a surgical plan personalized 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 personalized replacement implants.

- *iFit Just-in-Time Delivery* our just-in-time manufacturing and delivery capabilities. We manufacture the personalized replacement implants and iJigs to order and do not maintain significant inventory of finished products. We deliver the personalized replacement implants 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 personalized products and services

We use our iFit technology platform to develop personalized 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 personalized joint replacement implants offer significant benefits to patients, surgeons and hospitals or other medical facilities that are not afforded by standard, or "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 personalized 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 and/or plan our implants to match the patient's anatomy to provide a more stable, natural feeling joint. With regard to our personalized 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 individualized 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 personalized surgical plan and personalized 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 received our individualized pre-operative surgical plan or iView, that indicates where 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 individualized 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 personalized 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 Orthopedic Research Society, 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 personalized 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 system.

- **For the hospital, ambulatory surgical center or other medical facility.** We believe that our personalized 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 personalized 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 personalized 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 published in Reconstructive Review in 2019, of 62 patients with either our iTotal CR or an off-the-shelf implant in a “Fast Track” protocol, also indicates that a significantly higher (p≤0.05) proportion of iTotal CR patients (66%) were discharged in less than 1 day when compared to off-the-shelf patients (30%).

  - *Economic Savings*. We believe that our technology offers the potential of significant economic savings to hospitals 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 personalized individually made implants or off-the-shelf implants. In that study, the total average real hospital costs between the personalized 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 personalized 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 personalized 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 personalized 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 personalized 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.

- ***Seek to obtain enhanced reimbursement or create alternative payment models to enhance patient access and information.*** We believe that today's reimbursement system does not easily allow for patients to realize the value of our technology. Currently, hospitals and other medical facilities purchase implants for use in joint replacement. Because hospitals are typically paid a global fee that includes implant acquisition costs, we do not believe that hospitals' interests are completely aligned with patient interests. Hospitals, for example, are incentivized to obtain the lowest cost joint replacement system to maximize profits while patients may place greater weight on performance and other factors. While many hospitals may rely on surgeon recommendations regarding implant purchase decisions, the increasing trend toward hospital-employee physicians and gainsharing have created a disincentive for physicians to provide full information to patients about their decision-making process relating to, and evaluation of, various surgical options, including the price-versus-performance value tradeoff between various replacement systems. To address these trends, we support clinical studies to demonstrate the overall value of our implants to the healthcare system, which could become increasingly important in bundled care settings. We also educate surgeons, hospitals and third-party payors on our existing clinical and economic benefits. And we actively reach out to private insurers to discuss both their reimbursement policies and how we can collaborate on alternate payment models. Additionally, we provide patient-focused educational and marketing materials to better provide patients, in collaboration with their surgeons, the tools to make more informed decisions about the choices of joint replacement systems available to them.

- ***Broaden our product portfolio by launching additional personalized orthopedic implants and complementary non-individualized or standard implants.*** While our initial focus has been on the knee implant market, we believe our iFit technology platform is applicable to personalized 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 personalized hip replacement implant, which we launched on a limited basis in the second half of 2018. In November 2019, we received FDA clearance for and entered full commercial launch of the Conformis Hip System. We are planning for a limited commercial launch of a second stem for the Conformis Hip System in the second half of 2021. We launched on a limited basis our next generation iTotal CR Identity knee replacement implant in the second half of 2019 and are planning a full commercial launch for both the iTotal CR and PS Identity 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 are planning for a limited commercial launch of a femur cementless or Press Fit option for our iTotal knee implant in the first half of 2020 and a limited commercial launch of a tibia cementless or Press Fit option in the first half of 2021. We also expect a limited commercial launch of our full system Identity knee replacement implants in the second 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.

- ***Optimize 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 and/or off-shoring of appropriate 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 January 31, 2020, we own or exclusively in-license a total of approximately 356 issued patents and pending patent applications that cover personalized 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

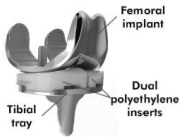
Knee replacement products

We offer a broad line of primary knee replacement implants, both partial and total, that we personalize through proprietary software and services to fit the individual patients. Surgeons use our family of personalized knee implants to treat mild to severe osteoarthritis of the knee. All of our knee replacement products and related design software have been cleared by the FDA under the premarket notification process of Section 510(k) of the FDCA. We also have received CE Mark certification for Europe and applicable geographies. We deliver our personalized 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:

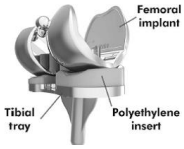
iTotal CR

iTotal CR is the only cruciate-retaining, personalized 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 personalized components.



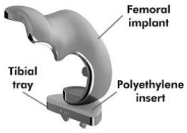
iTotal PS

The iTotal PS is the only posterior cruciate ligament substituting, or posterior-stabilized, personalized 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 personalized components.



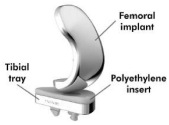
iDuo

The iDuo is the only personalized 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 personalized components.



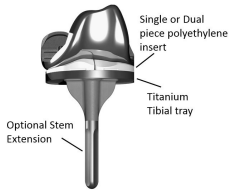
iUni

The iUni is a personalized 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.



iTotal IDENTITY

Building off the legacy of the iTotal platform the iTotal® Identity is Conformis' newest patient-specific knee system. The customized femur and new titanium tibial implant are designed to fit specific anatomy to reduce sizing compromises and allow for optimal bone preservation. The knee system is delivered in a single, pre-sterilized kit with surgeon selected polyethylene inserts. Identity incorporates new design features such as tibial stem extensions, and refined patient-specific instrumentation (PSI), to provide a more traditional bone-cutting experience.



Hip replacement products

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 reusable instrument trays and 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 November 6, 2019, we received FDA 510(k) clearance for our full commercial release of the Conformis Hip System product, and we market-launched the system on November 11, 2019. 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 and offset correction. Our Conformis Hip System provides a femoral stem with a patient-specific neck and the planned sizes for the acetabular cup, liner and head. Combined with the Hip iView, our Conformis Hip System 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 January 31, 2020, over 31 surgeons have implanted an aggregate of more than 481 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 personalized 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.

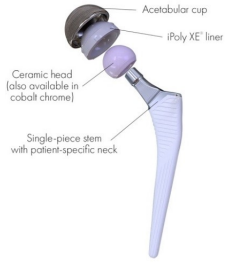
The following is an overview of our Conformis Hip System:

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.



Cordera Hip System

In addition to the patient-specific Hip System, we received FDA 510(k) clearance on August 28, 2019 for an off-the-shelf Cordera Hip System. The stems are offered in the same sizes as the patient-specific system and come in two standard neck angles and two standard neck lengths. Combined with our existing head and acetabular cup line, we can offer a standard off-the-shelf system, with or without surgical pre-planning and without the wait for personalization. The Cordera Hip System, similar to standard off-the-shelf systems, does not offer personalized neck lengths, neck angles or versions.

Our proprietary iJigs

Our iJigs are personalized, 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 personalized implant to the patient. We believe that providing our iJigs with our personalized 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 personalized 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 personalized 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 personalized 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 personalized knee implants with off-the-shelf knee implants. As of January 31, 2020, there have been more than 30 peer-reviewed journal articles and numerous abstracts either presented or accepted for presentation at conferences reporting on the results of clinical studies of our personalized 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, Australia, Argentina, Benelux, United Arab Emirates, Italy and Greece. We expect that our international activities will increase over the foreseeable future as we continue to pursue opportunities in additional international markets. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Consolidated results of operations—Product 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 personalized 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 personalized 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 products and services 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 personalized products to a larger customer base, which we refer to as mass personalization.

Our team of 25 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, 2019, and 2018, company-sponsored research and development expense was $12.5 million, and $16.9 million, respectively.

When we develop a new product or seek to improve our existing products, our team of biomechanical, process 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.

Our design services include the production of unique, individualized, computer-aided designs ("CAD" or "CAD designs") on a per-patient basis either in-house and/or through a third party in India. We use the result of these design services to direct a majority of our product manufacturing efforts. As part of our manufacturing cost reduction efforts we have implemented, 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 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 personalized 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. 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 personalized joint replacement implants, which we believe will reduce costs associated with the design process; and
- obtain more favorable pricing of certain components of our products manufactured for us by third parties.

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

iFit 3D printing

We believe that 3D printing is especially suited for production of our 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 audits our suppliers on a set interval and schedule 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 personalized 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 personalized implants and iJigs.

Patent rights

As of January 31, 2020, we owned or exclusively in-licensed 285 issued patents around the world, including 158 patents issued in the United States and 127 foreign patents.

- With respect to the patents that we own relating primarily to our personalized 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 2033.
- 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 January 31, 2020, we owned or exclusively in-licensed 71 patent applications, including 21 patent applications pending in the United States and 50 foreign patent applications.

- With respect to the patent applications that we own relating primarily to our personalized 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 2022 and 2034. Our patent portfolio covers a range of subject matter, including:

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

License agreement with Stryker

On September 30, 2019, we entered into an Asset Purchase Agreement with Howmedica Osteonics Corp., a subsidiary of Stryker Corporation also known as Stryker Orthopaedics or Stryker. In connection with entering into the Asset Purchase Agreement, we also entered into a Development Agreement, a License Agreement, and other ancillary agreements contemplated by the Asset Purchase Agreement with Stryker. Under the terms of the agreements, we agreed to sell and license to Stryker certain assets relating to our patient-specific instrumentation technology, and to develop, manufacture, and supply patient-specific instrumentation for use in connection with Stryker's "off-the-shelf" non-personalized knee implant offerings. We received $14 million upfront and will receive up to an additional $16 million in milestone payments pursuant to the License Agreement and the Development Agreement. Under the long-term Distribution Agreement, we will supply patient-specific instrumentation to Stryker. We may be required to pay back a portion of the initial payment as it is contingent on the successful completion of milestones set forth in the Development Agreement and License Agreement.

Trademarks

As of January 31, 2020, we have filed 142 trademark registrations in the United States and in other major markets worldwide, including the following marks: Conformis, iFit, iTotal, iDuo, and iUni. We have 1 trademark application 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 hospital customers for our products vary 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 who offer a standard off-the-shelf-implant, 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 personalized 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, May 26, 2024 for our iDuo product. Our iTotal PS product CE Certificate of Conformity expires on March 5, 2020 and we expect to receive a renewal certificate before expiration. 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 applicable requirements of 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 with 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. Major Quality System updates, including Clinical Evaluation and Post Market Surveillance, are complete and being rolled out. The technical documentation updates for our first product

to require MDR CE Marking are underway. Our EU MDR Quality System audit was accepted by the Notified Body and we are currently awaiting the scheduling date for our Quality System audit, which will include witness tests and reconciliation activities during on-site audits to ensure that the quality management system is working properly. We expect to be compliant with the applicable requirements of the EU MDR by 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% and 11%, respectively. 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 2019, sales in Germany represented 10% 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—Summary of Significant Accounting Policies" 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—Segment and Geographic Data" 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 January 31, 2020, we had 271 employees, including 262 full-time employees, 38 of whom were engaged in sales and marketing, 31 in research and development, 125 in manufacturing and service, 43 in regulatory, clinical affairs and quality activities and 34 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 website at http://www.sec.gov. We also make available, free of charge on our website www.conformis.com, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. The information contained on, or that can be accessed through, our website is not a part of or incorporated by reference in this Annual Report on Form 10-K.

ITEM 1A. *RISK FACTORS*

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

Risks related to our financial position

We have incurred losses in the past, expect to 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 $28 million for the year ended December 31, 2019, and $43 million for the year ended December 31, 2018. As of December 31, 2019, we had an accumulated deficit of $504 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 then 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.

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., ("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.

Our Loan and Security Agreement (the "2019 Secured Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP ("Innovatus"), as collateral agent and lender, East West Bank and the other lenders party thereto from time to time (collectively, the "Lenders"), provides for term loans and a revolving credit facility to repay existing indebtedness, for working capital and general business purposes, in a principal amount of up to $30 million. The term loan facility established under the 2019 Secured Loan Agreement is secured by substantially all of our and our U.S. subsidiaries' properties, rights and assets. The 2019 Secured Loan Agreement includes a trailing six months' revenue test, a liquidity covenant and an additional liquidity covenant that is applicable if there are borrowings under the revolving credit facility. The 2019 Secured Loan Agreement also includes customary representations, affirmative and negative covenants. Additionally, the 2019 Secured Loan Agreement 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 Innovatus, as collateral agent, with the right to accelerate all obligations under the 2019 Secured Loan Agreement and 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 insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $250,000, one or more judgments against us in an amount greater than $500,000, changes with respect to governmental approvals and FDA actions.

2017 Secured Loan Agreement

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. On June 25, 2019, the Company elected to prepay the remainder of the Oxford term loan outstanding (along with accrued interest and applicable final payment and prepayment fee) using the proceeds from the 2019 Secured Loan Agreement. The prepayment of the debt was accounted for as a debt extinguishment and the Company incurred a loss on the extinguishment recognized in Interest expense of $1.1 million. 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.

2019 Secured Loan Agreement

On June 25, 2019, the Company entered into a new loan and security agreement (the “New Credit Agreement”) with Innovatus Life Sciences Lending Fund I, LP (“Innovatus”), as a collateral agent and lender, East West Bank (the “Bank”) and the other lenders party thereto from time to time (collectively, the “Lenders”), pursuant to which the Lenders agreed to make term loans and a revolving credit facility to the Company to repay existing indebtedness, for working capital and general business purposes, in a principal amount of up to $30 million (the "2019 Secured Loan Agreement"). We used the proceeds from the 2019 Secured Loan Agreement to pay off the $15 million term loan from Oxford Finance LLC.

The term loan facility established under the New Credit Agreement is secured by substantially all of the Company’s and its U.S. subsidiaries’ properties, rights and assets.

The 2019 Secured Loan Agreement includes a trailing six months' revenue test, a liquidity covenant and an additional liquidity covenant that is applicable if there are borrowings under the revolving credit facility. The term loan under the New Credit Agreement bears interest at a floating annual rate calculated at the greater of the variable rate of interest as most recently announced by the Bank as prime or 5.50%, plus 3.75% (“Term Loan Basic Interest Rate”). The Company is required to make monthly interest only payments in arrears on the term loan for four years; provided that the Company has elected to pay 2.50% per annum of such Term Loan Basic Interest Rate in-kind by adding an amount equal to 2.50% per annum of the outstanding principal amount to the then outstanding principal balance on a monthly basis until the third anniversary of the New Credit Agreement. Commencing on July 1, 2023, and continuing on the payment date of each month thereafter, the Company is required to make consecutive equal monthly payments of principal of the term loan, together with accrued interest, in arrears, to the Lenders. All unpaid principal, accrued and unpaid interest with respect to the term loan, and a final fee in the amount of 5.0% of the term loan commitment, is due and payable in full on the term loan maturity date of June 1, 2024. Under the New Credit Agreement, the Bank will make loans of up to $10,000,000 from time to time outstanding, subject to availability based on a borrowing base equal to (i) 85.00% of eligible accounts, subject to a maximum of 2.50% dilution based upon collections, minus (ii) the Company’s foreign accounts receivable credit insurance’s outstanding co-payment and minimum annual deductible (that has not been used at the applicable time). Advances under the revolving credit facility bear interest at a rate of 0.50% above the Bank’s prime rate. Interest on the revolving advances is payable monthly in arrears and the principal is due in full on June 1, 2024.

At the Company’s option, the Company may prepay all, but not less than all, of the term loans advanced by the Lenders under the term loan facility after the first year, 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 fee, plus all other amounts that are due and payable, including the Lenders’ expenses and interest at the default rate with respect to any past due amounts.

The 2019 Secured Loan Agreement also includes customary representations, affirmative and negative covenants. Additionally, the 2019 Secured Loan Agreement 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 Innovatus, as collateral agent, with the right to accelerate all obligations under the 2019 Secured Loan Agreement and 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 insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $250,000, one or more judgments against us in an amount greater than $500,000, changes with respect to governmental approvals and FDA actions.

The term loan under the New Credit Agreement replaces the Company’s prior credit facility established under the Loan and Security Agreement with Oxford Finance LLC, as a collateral agent, and the lenders party thereto from time to time, dated as of January 6, 2017, as amended by that certain First Amendment to Loan and Security Agreement dated as of March 9, 2017, that certain Second Amendment to Loan and Security Agreement dated as of June 30, 2017, that certain Third Amendment to Loan and Security Agreement dated as of December 18, 2017, that certain Fourth Amendment to Loan and Security Agreement dated as of July 31, 2018 and that Fifth Amendment to Loan and Security Agreement dated as of December 13, 2018. For further information regarding this facility, see “Note K—Debt and Notes Payable-2019 Secured Loan Agreement” in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

Our obligations under the 2019 Secured Loan Agreement, and our other financial obligations and contractual commitments, including any additional indebtedness that we may incur, could increase our vulnerability to adverse changes in general economic, industry and market conditions; limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and place us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options. 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 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, 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 full commercial launch of the Conformis Hip System, for which we received FDA clearance in November 2019.

On September 30, 2019, we entered into an Asset Purchase Agreement with Howmedica Osteonics Corp., a subsidiary of Stryker Corporation also known as Stryker Orthopaedics ("Stryker"). In connection with entering into

the Asset Purchase Agreement, we also entered into a Development Agreement, a License Agreement, and other ancillary agreements contemplated by the Asset Purchase Agreement with Stryker. Under the terms of the agreements, the Company agreed to sell and license to Stryker certain assets relating to the Company's patient-specific instrumentation technology, and to develop, manufacture, and supply patient-specific instrumentation for use in connection with Stryker's "off-the-shelf" non-personalized knee implant offerings. The Company received $14 million upfront and will receive up to an additional $16 million in milestone payments pursuant to the License Agreement and the Development Agreement. Under the long-term Distribution Agreement, the Company will supply patient-specific instrumentation to Stryker. The Company may be required to pay back a portion of the initial payment as it is contingent on successful completion of milestones set forth in the Development Agreement and License Agreement.

Any factors that delay the commercial launch of additional products or result in sales of additional products increasing at a lower rate than expected, could adversely affect our business, financial condition and operating 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 design and manufacture our personalized replacement implants and iJigs to order and do not maintain significant inventory of finished product. We deliver the personalized 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;
- obtain enhanced payment for our design services;
- negotiate more favorable acquisition 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;
- 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 "individualized," "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 personalized 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-personalized, 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 Conformis Hip System replacement product. 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 on our iTotal knee replacement product. 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 personalized joint replacement products is shorter than that of off-the-shelf products. In an October 2019 report from Beyond Compliance, results were presented summarizing five-year data from the England and Wales National Joint Registry demonstrating high survivorship in patients treated with the iTotal CR knee replacement implant, specifically the data showed a low cumulative percent revision of 1.8% for our patients as compared with 2.2% 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 payors 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.

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. For example, during 2019, denials of coverage from Aetna, the third largest commercial payor, negatively impacted our product revenue in the United States. On December 5, 2019, we learned that, although Aetna updated its policy, it did not change its coverage position with respect to our products. 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 can be considered. We believe that these guidelines are directed to patient-specific instruments with off-the-shelf implants, not patient-specific instruments with personalized 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 might 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 ACO's 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, became effective on January 1, 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.” On December 20, 2019, President Trump signed into law the 2020 federal spending package, which includes a provision to permanently repeal the 2.3% medical device excise tax. 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 91% of our total revenue from sales of our products in the United States for the year ended

December 31, 2019, and approximately 84% of our total revenue from sales of our products in the United States for the year ended December 31, 2018. We do not have independent sales representatives outside 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, 2019 and 2018. Revenue generated from the sales of our products to distributors represented approximately 40% and 30% of our total revenue from sales of our products outside the United States for the years ended December 31, 2019 and 2018. We did not have distributors within the United States and, therefore, did not generate any revenue from sales of our products to distributors in the United States in the years ended December 31, 2019 and 2018. 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.

Not all 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 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.

As a result of "Brexit," the United Kingdom (UK) departed the European Union (EU) at midnight on January 31, 2020. This will be followed by a transition period, which will last until December 31, 2020 unless extended. Since the regulatory framework for medical devices in the UK, 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 UK. It remains to be seen how, if at all, Brexit will impact regulatory requirements for medical device candidates and medical devices in the UK.

We have received CE Marking for all of our products to date through the British Standards Institution, or BSI, a UK notified body. In the absence of a withdrawal agreement, BSI would no longer be recognized as a notified body for the EU and we could not use our current CE Marks on our products when sold into the EU. To address this concern, BSI has formed a notified body entity in the Netherlands and we participated in a migration of our CE Marks from BSI's UK entity to BSI's affiliate in the Netherlands. Such migration allows us to sell into both the EU and the UK, as the Medicines and Healthcare Products Regulatory Agency, or MHRA, in the UK, has indicated that they would continue to accept CE Marking from European notified bodies.

The consideration and passage of the Referendum of the UK's Membership of the European Union, providing for the exit of the UK from the EU, could adversely affect our sales in the UK and the EU, as well as our existing and future customers and employees in EU. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU 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. For example, in December 2019, we received a warning letter from the FDA concerning the number of sterilization cycle failures relating to Vaporized Hydrogen Peroxide (“VHP”) sterilizers that we use as a limited, alternative sterilization method for a small quantity of products. In response to the warning letter, we have completed all appropriate process and/or equipment validations of our manufacturing processes for implant components and instrumentation manufactured at our Wilmington and Wallingford facilities. However, delays in validation of revised or new manufacturing processes or FDA clearance of new manufacturing processes could impact our ability to grow our business in the future.

Our current and planned future products are complex and require the integration of a number of separate components and processes. To become profitable, we must manufacture our products in increased quantities in compliance with regulatory requirements and at an acceptable cost. Increasing our capacity to manufacture our products on this scale may require us to introduce new manufacturing processes, vertical integration of the manufacturing process by performing machining, polishing and other finishing services in-house, and to improve internal efficiencies. We have 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 transitioned CAD labor force in 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, terrorist attacks, or the occurrence of a contagious disease or illness, such as the novel coronavirus, 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 timeframes 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, natural disasters and contagious diseases or illnesses, such as the novel coronavirus, 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 personalized 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 cybersecurity 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 cybersecurity incidents. There can be no assurance that we will not be subject to cybersecurity 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, cybersecurity 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 cybersecurity 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, Australia, Argentina, Benelux, United Arab Emirates, Italy and Greece. 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, 2019 and 2018 approximately 12% and 13% of our revenue was attributable to our international customers, respectively, and as of December 31, 2019, approximately 3% 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 and the United Kingdom's exit from the European Union (Brexit).

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 efforts to expand our growth

We plan to grow our organization in accordance with a new long-range business plan, and as a result, we may encounter difficulties in managing 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 has required 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. For example, during 2019 each of our former Chief Financial Officer and former Chief Legal Officer resigned from

the Company. 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 partes 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 partes review proceedings initiated 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 August 15, 2019, we filed a lawsuit against Zimmer Biomet Holdings, Inc. and Zimmer, Inc., or "Zimmer Biomet," and, on August 29, 2019, we filed a lawsuit against Medacta USA, Inc., or "Medacta," both in the United States District Court for the District of Delaware. In both cases, we are seeking damages for the defendants' infringement of certain of the Company's patents related to patient-specific instrument and implant systems. On November 5, 2019, Zimmer Biomet countersued, filing claims alleging that our products infringe certain patents owned by Zimmer Biomet. These lawsuits are 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;
- 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 joint 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 in the 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 in the future, be 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 claim against us, regardless of 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. In particular, 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 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, May 26, 2024 for our iDuo product. Our iTotal PS product CE Certificate of Conformity expires on March 5, 2020 and we expect to receive a renewal certificate before expiration. 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. Major Quality System updates are complete, our application for EU MDR Quality System audit was accepted, technical documentation updates are underway and we expect to be compliant with the EU MDR on or before May 2020.

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.

We are also subject to other types of government regulation which could have an adverse effect on our business. For example, certain of our manufactured components can be sterilized using Ethylene Oxide (“EO”) sterilization. In the United States, several regulators, including the U.S. Environmental Protection Agency (“EPA”), U.S. Food and Drug Administration (“FDA”), and agencies at the state and local level, regulate the use of EO sterilization. Recent announcements of the temporary or permanent closure of EO sterilization facilities have been associated with state and/or local regulatory or other legal action related to EO emissions at those facilities. Regulatory, legislative, or legal action that curtails or eliminates EO sterilization may have a material adverse effect on our financial condition and results of operations.

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 healthcare 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 and Wilmington, Massachusetts facilities in 2019, the FDA issued to us two Form 483s with several observations, including deviations from the QSR. In December 2019, we received a warning letter to our Wilmington facility from the FDA concerning the number of sterilization cycle failures relating to Vaporized Hydrogen Peroxide ("VHP") sterilizers at our Wilmington facility that we use as a limited, alternative sterilization method for a small quantity of products. We have responded to both the Form 483s and the warning letter, including revalidations and continued emergency use of the VHP sterilizers. The FDA has received our responses to the warning letter and indicated that it did not have any additional questions at this time. All observations have been addressed for the Billerica Form 483 relating to the Billerica facility and the inspection closed. A single item remains to be closed for the Wilmington facility. We continue to take various corrective and preventative actions to improve our quality, production and design control systems. We offered to provide the FDA with periodic progress updates regarding these matters and the FDA accepted. 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 relationships with healthcare providers, physicians and third -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 prior 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. Although we regained compliance with the listing requirements, we may in the future fail to satisfy the Nasdaq Global Select Market's continued listing requirements. In such an event, 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;
- 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 24.5035% of our capital stock as of December 31, 2019. 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, 2019, we had federal net operating loss, or NOL, carryforwards of $414 million and state NOL carryforwards of $236 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 August 15, 2019, we filed a lawsuit against Zimmer Biomet Holdings, Inc. and Zimmer, Inc., or "Zimmer Biomet," in the United States District Court for the District of Delaware seeking damages for Zimmer Biomet's infringement of certain of the Company's patents related to patient-specific instrument and implant systems. The complaint alleges that Zimmer Biomet's multiple lines of patient-specific instruments, as well as the implant components used in conjunction with them, infringe four of our patents. The accused product lines include Zimmer Biomet patient-specific instrument and implant systems for knee, shoulder, and hip replacement procedures. On November 5, 2019, Zimmer Biomet filed a lawsuit against us in the United States District Court for the District of Delaware, alleging that we infringe five patents owned by Zimmer Biomet. Zimmer Biomet alleges that our iTotal CR and iTotal PS products infringe all five asserted patents, that our iDuo product infringes three of the asserted patents, and that our iUni product infringes two of the asserted patents. On January 13, 2020, Zimmer Biomet filed a motion to dismiss our complaint, and we filed our answer to Zimmer Biomet's complaint, denying that our products infringe Zimmer Biomet's asserted patents. Our answer also alleges that Zimmer Biomet's asserted patents are invalid.

On August 29, 2019, we filed a lawsuit against Medacta USA, Inc. "Medacta," in the United States District Court for the District of Delaware, and we amended our complaint on December 23, 2019, seeking damages for Medacta's infringement of certain of our patents related to patient-specific instrument and implant systems. We allege in the lawsuit that Medacta's multiple lines of patient-specific instruments, as well as the implant components used in conjunction with them, infringe four of our patents. The accused product lines include Medacta patient-specific instrument and implant systems for knee and shoulder replacement procedures. On January 6, 2020, Medacta filed its answer, denying that its patient-specific instrument and implant systems infringe the patents asserted by us. Medacta's answer also alleges the affirmative defense that our asserted patents are invalid.

Adverse outcomes of these lawsuits could have a material adverse effect on the Company's business, financial condition or results of operations. The Company is presently unable to predict the outcome of these lawsuits or to reasonably estimate a range of potential losses, if any, related to the lawsuits.

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.

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, 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
Year ended December 31, 2019:		
First Quarter	$ 2.88	$ 0.39
Second Quarter	$ 4.71	$ 2.11
Third Quarter	$ 4.12	$ 1.49
Fourth Quarter	$ 2.55	$ 1.45

Holders of Our Common Stock

As of February 28, 2020, there were approximately 287 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

Not applicable.

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 personalized, to fit each patient's unique anatomy. The worldwide market for joint replacement products is approximately $18.9 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 personalized knee implants designed to restore the natural shape of a patient's knee. We have sold a total of more than 110,000 knee implants, more than 87,000 total knee implants and 22,000 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. On November 7, 2019, we announced FDA clearance of the next generation Conformis Hip System, and initiated the full commercial launch of the Conformis Hip System.

Our iFit technology platform comprises three key elements:

- *iFit Design*, our proprietary algorithms and computer software that we use to design personalized 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 personalized 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, Australia, Argentina, Benelux, United Arab Emirates, Italy and other markets. 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 typically 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.

Ongoing 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 ongoing 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.

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, polyethylene tibia tray inserts used in our total knee implants, and our patient-specific Conformis Hip System implants in our facility in Wilmington, Massachusetts. We polish our femoral implants used in our total and partial knee products in our facility in Wallingford, Connecticut. Starting in 2019, we began to manufacture the lateral partial tibial tray components 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 personalized 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; and
- developing new releases of our software used in the design of our personalized joint replacement implants, which we believe will reduce costs associated with the design time.

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 (expenses), 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, debt extinguishment loss, and 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, 2019 and 2018

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

	2019		2018		2019 vs 2018	
Years Ended December 31,	Amount	As a% of Total Revenue	Amount	As a% of Total Revenue	$ Change	% Change
Revenue						
Product revenue	$ 76,649	99 %	$ 78,627	88 %	$ (1,978)	(3)%
Royalty	780	1	11,162	12	(10,382)	(93)
Total revenue	77,429	100	89,789	100	(12,360)	(14)
Cost of revenue	40,692	53	41,304	46	(612)	(1)
Gross profit	36,737	47	48,485	54	(11,748)	(24)
Operating expenses:						
Sales and marketing	28,514	37	38,955	43	(10,441)	(27)
Research and development	12,457	16	16,869	19	(4,412)	(26)
General and administrative	20,895	27	24,622	27	(3,727)	(15)
Goodwill impairment	—	—	6,731	7	(6,731)	(100)
Total operating expenses	61,866	80	87,177	97	(25,311)	(29)
Loss from operations	(25,129)	(32)	(38,692)	(43)	13,563	35
Total other income/(expenses), net	(3,304)	(4)	(4,612)	(5)	1,308	28
Loss before income taxes	(28,433)	(37)	(43,304)	(48)	14,871	34
Income tax provision	45	—	61	—	(16)	(26)
Net loss	$ (28,478)	(37)%	$ (43,365)	(48)%	$ 14,887	34 %

Product revenue. Product revenue was $76.6 million for the year ended December 31, 2019 compared to $78.6 million for the year ended December 31, 2018, a decrease of $2.0 million or 3%, due principally to decreased sales of our iTotal CR and partial knee products, partially offset by increased sales of our iTotal PS and Hip Systems. Our sales during the second half of 2019 were negatively impacted by denials in coverage from Aetna.

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):

	2019		2018		2019 vs 2018	
Years Ended December 31,	Amount	As a % of Product Revenue	Amount	As a % of Product Revenue	$ Change	% Change
United States	$ 67,151	88%	$ 68,062	87%	$ (911)	(1)%
Germany	7,598	10	9,007	11	(1,409)	(16)
Rest of world	1,900	2	1,563	2	337	22
Product revenue	$ 76,649	100%	$ 78,627	100%	$ (1,978)	(3)%

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 88% for the year ended December 31, 2019 compared to 87% for the year ended December 31, 2018. We believe the higher level of revenue as a percentage of product revenue inside the United States in 2019 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 $0.8 million for the year ended December 31, 2019 compared to $11.2 million for the year ended December 31, 2018, a decrease of $10.4 million or 93.0%. The decrease was driven by the $10.5 million royalty payment under the Settlement and License Agreement with Smith and Nephew from 2018 partially offset by higher ongoing royalty revenue from MicroPort Orthopedics Inc.

Cost of revenue, gross profit and gross margin. Cost of revenue was $40.7 million for the year ended December 31, 2019 compared to $41.3 million for the year ended December 31, 2018, a decrease of $0.6 million or 1%. The decrease was due primarily to lower volumes. Gross profit was $36.7 million for the year ended December 31, 2019 compared to $48.5 million for the year ended December 31, 2018, a decrease of $11.7 million or 24%. Gross margin was 47% for the year ended December 31, 2019 compared to 54% for the year ended December 31, 2018, a decrease of 700 basis points. The decrease in gross margin was driven primarily by the $10.5 million royalty received under the Settlement and License Agreement with Smith & Nephew in 2018, which contributed 600 basis points of the decrease. The remaining decrease in gross margin was primarily driven by lower average selling prices and foreign exchange headwinds.

Sales and marketing. Sales and marketing expense was $28.5 million for the year ended December 31, 2019 compared to $39.0 million for the year ended December 31, 2018, a decrease of $10.4 million or 27%. The decrease was due primarily to decreases in personnel costs of $5.2 million, marketing program and public relations spending of $3.5 million, $1.9 million in commissions, and $0.2 million in other sales and marketing expenses. The decreases are partially offset by an increase in reusable instrumentation depreciation of $0.4 million. Sales and marketing expense decreased as a percentage of total revenue to 37% for the year ended December 31, 2019 compared to 43% the year ended December 31, 2018.

Research and development. Research and development expense was $12.5 million for the year ended December 31, 2019 compared to $16.9 million for the year ended December 31, 2018, a decrease of $4.4 million or 26%. The decrease was due to decreases of $1.9 million in personnel costs, $1.6 million in revenue share and clinical trial expenses, and $1.0 million in professional consulting and prototyping expense, partially offset by $0.1 million increase in other research and development expenses. Research and development expense decreased as a percentage of total revenue to 16% for the year ended December 31, 2019 from 19% for the year ended December 31, 2018.

General and administrative. General and administrative expense was $20.9 million for the year ended December 31, 2019 compared to $24.6 million for the year ended December 31, 2018, a decrease of $3.7 million or 15%. The decrease in expenses was due to $2.6 million in impairment and long-lived asset disposal charges, $1.2 million in personnel costs, and $0.9 million in legal expenses. The decreases were partially offset by increases in outbound freight costs of $0.2 million, insurance premiums of $0.2 million, professional services of $0.4 million, and other general and administration expenses of $0.2 million. General and administrative expense remained consistent as a percentage of total revenue to 27% for the years ended December 31, 2019 and December 31, 2018.

Goodwill impairment. Goodwill impairment was $6.7 million for the year ended December 31, 2018. 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 $3.3 million for the year ended December 31, 2019 compared to a net expense of $4.6 million for the year ended December 31, 2018, a change of $1.3 million, or 28%. The change was primarily due to $0.7 million in unrealized foreign exchange transaction loss in 2019 compared to $1.9 million unrealized foreign exchange transaction loss in 2018, which was attributable to the effect of exchange rate change on non-permanent intercompany debt with our foreign subsidiaries, a decrease of $0.9 million in interest expense associated with our term debt, a reduction in interest income from investments of $0.3 million, and an increase of $0.5 million related to expenses incurred related to early payoff of the Oxford Term Loans.

Income taxes. Income tax provision was $45,000 for the year ended December 31, 2019 and $61,000 for the year ended December 31, 2018. We continue to generate losses for U.S. federal and state tax purposes and have net operating loss carryforwards creating a deferred tax asset. We maintain a full valuation allowance for deferred tax assets.

Liquidity, capital resources and plan of operations

Sources of liquidity and funding requirements

Since our inception in 2004, we have financed our operations primarily through private placements of preferred stock, our initial public offering in 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, 2019, we had an accumulated deficit of $504.1 million.

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.

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, 2019, we sold 1,870,069 Shares under the Distribution Agreement resulting in net proceeds of $3.6 million.

On December 17, 2018, we entered into a stock purchase agreement with Lincoln Park Capital ("LPC" and the "LPC Agreement"). Upon entering into the LPC Agreement, 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. Additionally, as consideration for LPC's commitment to purchase shares of common stock under the LPC Agreement, 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 not to exceed 12,297,210 over a 36-month period subject to the terms of the LPC Agreement. 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 Agreement. 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 Agreement, 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 Agreement, 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 Agreement) is below a floor price of $0.25 per share. No warrants, derivatives, financial or business covenants are associated with the LPC Agreement 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 Agreement may be terminated by us at any time, at our sole discretion, without any cost or penalty. As of December 31, 2019, the Company has sold 2,276,398 Shares under the APC Agreement resulting in net proceeds of $1.0 million.

On June 25, 2019, we entered into a Loan and Security Agreement (the "2019 Secured Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP ("Innovatus"), as collateral agent and lender, East West Bank and the other lenders party thereto from time to time (collectively, the "Lenders"), pursuant to which the Lenders agreed to make term loans and revolving credit facility to the Company to repay existing indebtedness, for working capital and general business purposes, in a principal amount of up to $30 million, comprised of a $20 million term loan and up to $10 million revolving credit facility. The Company used $15 million of the proceeds from the debt financings to pay off its 2017 Secured Loan Agreement with Oxford and the remaining proceeds will be utilized to fund the operations of the business. In addition, Innovatus purchased approximately $3 million of the Company's common stock at the previous day's closing price. For further information regarding the 2017 Secured Loan Agreement and the 2019 Secured Loan Agreement, see “Note K—Debt and Notes Payable” in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

On September 30, 2019, we entered into an Asset Purchase Agreement with Howmedica Osteonics Corp., a subsidiary of Stryker Corporation also known as Stryker Orthopaedics ("Stryker"). In connection with entering into the Asset Purchase Agreement, we also entered into a Development Agreement, a License Agreement, and other ancillary agreements contemplated by the Asset Purchase Agreement with Stryker. Under the terms of the agreements, we agreed to sell and license to Stryker certain assets relating to the Company's patient-specific instrumentation technology, and to develop, manufacture, and supply patient-specific instrumentation for use in connection with Stryker's "off-the-shelf" non-personalized knee implant offerings. We received $14 million upfront and will receive up to an additional $16 million in milestone payments pursuant to the License Agreement and the Development Agreement. As of December 2019, we successfully completed one out of the three total milestones. We may be required to pay back a portion of the initial payment as it is contingent on successful completion of milestones set forth in the Development and License agreements. Under the long-term Distribution Agreement, we will supply patient-specific instrumentation to Stryker.

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, completion of the milestones set forth in the Development Agreement and License Agreement with Stryker, 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, 2019, we had cash and cash equivalents and investments of $26.4 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 as of December 31, 2019, anticipated revenue from operations, our ability to issue equity to LPC, and our ability to draw down on the line of credit 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. In order for us to meet our operating plan beyond this timeframe, gross margin improvements and operating expense reductions will be necessary to reduce cash used in operations, and we will need to successfully complete milestones set forth in the Development and License Agreements. 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 revenue, operating expense reductions. 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,			
	2019	2018	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$ (2,838)	$ (25,176)	$ 22,338	89 %
Investing activities	4,324	15,626	(11,302)	(72)
Financing activities	8,527	7,655	872	11
Effect of exchange rate on cash	1	(73)	74	101
Total	$ 10,014	$ (1,968)	$ 11,982	609 %

Net cash used in operating activities. Net cash used in operating activities was $2.8 million for the year ended December 31, 2019 and $25.2 million for the year ended December 31, 2018, a decrease of $22.3 million. These amounts primarily reflect net losses of $28.5 million for the year ended December 31, 2019 and $43.4 million for the year ended December 31, 2018. Non-cash reconciling items between Net loss and cash used in operations for the year ended December 31, 2019 improved relative to December 31, 2018 due to the goodwill impairment of $6.7 million and $2.4 million in other asset impairment that were recorded in 2018, and stock-based compensation expense of $1.0 million, partially offset by a $1.5 million decrease from other non-cash items. The remaining change is related to decreases in our operating assets and liabilities, including contract liabilities of $12.0 million, and advances for research and development of $3.8 million related to the Development Agreement with Stryker, accounts receivable of $2.0 million and $2.7 million from accounts payable and accrued liabilities. The decreases are partially offset by increases from prepaid and other assets of $2.2 million and inventory of $2.2 million.

Net cash provided by investing activities. Net cash provided by investing activities was $4.3 million for the year ended December 31, 2019 compared to $15.6 million cash provided by investing activities for the year ended December 31, 2018, a decrease of $11.3 million. These amounts primarily reflect a decrease of $12.4 million from the net purchase and maturity of investment securities classified as available-for-sale, along with a $1.1 million reduction in purchases of property and equipment.

Net cash provided by financing activities. Net cash provided by financing activities was $8.5 million for the year ended December 31, 2019 and $7.7 million for the year ended December 31, 2018, an increase of $0.9 million. The increase was due to $20.0 million from proceeds from the issuance of debt, and $0.2 million from debt prepayment fees related to the Oxford term loan, partially offset by decreases of $17.7 million net proceeds from the issuance of common stock and $1.7 million from debt issuance costs and costs associated with the extinguishment of the Oxford term loan.

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 personalized 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 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. We incurred revenue share expense for Dr. Lang of $0.7 million for the year ended December 31, 2018. Dr. Lang was not a related party in 2019.

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 $2.0 million during the year ended December 31, 2019, and representing 2.6% of product revenue, $3.1 million during the year ended December 31, 2018, representing 4.0% 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, 2019, 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, and valuation of right-of-use assets and liabilities. 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, Australia, Argentina, United Arab Emirates, Italy, British Virgin Islands, and Benelux. 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, 2019. 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.

Ongoing 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 were 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 ongoing 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.

On September 30, 2019 we entered into an Asset Purchase Agreement with Stryker. In connection with entering into the Asset Purchase Agreement, we also entered into a Development Agreement, a License Agreement, and other ancillary agreements contemplated by the Asset Purchase Agreement with Stryker. Under the terms of the Stryker Agreements, we agreed to sell and license to Stryker certain assets relating to the Company's patient-specific instrumentation technology, and to develop, manufacture, and supply patient-specific instrumentation for use in connection with Stryker's "off-the-shelf," non-personalized knee implant offerings. We received $14 million upfront and will receive up to an additional $16 million in milestone payments pursuant to the License Agreement and the Development Agreement. We successfully completed one out of three milestones as of December 31, 2019. Under the long-term Distribution Agreement, we will supply patient-specific instrumentation to Stryker. The Agreements contain termination provisions whereas under certain circumstances, Stryker may be able to terminate the Development Agreement and a portion of the initial upfront payment is to be repaid to Stryker. Conversely, under certain circumstances, Stryker could terminate and pay an additional fee for the right to retain use of our intellectual property to sell patient-specific instrumentation with their off-the-shelf knee offering, subject to a sales-based royalty fee.

We determined that the Asset Purchase Agreement and the License Agreement is within the scope of ASC 606. Under the Asset Purchase and License Agreements, we are required to provide certain assets and the right to use the license for a specific purpose. The assets and the right to use the license are highly interdependent and is considered one performance obligation. The transaction price of $25.0 million was determined using the residual approach under ASC 606 by deducting the other services (development) performed under the agreement noting the arrangement does not contain a significant financing component.

We recognize a contract liability when there is an obligation to transfer goods or services and consideration has already been received from the customer. At December 31, 2019 we had $12.0 million recognized as a long-term contract liability related to consideration received from Stryker under the Asset Purchase and Development Agreements. We concluded the license rights under the License Agreement is functional and will be recognized at the point in time when FDA 510(k) clearance is received as required under Milestone 3 in the License Agreement, or upon Stryker's election to terminate and purchase the license rights.

Accounts receivable and allowance for doubtful accounts

Accounts receivable consist of billed and unbilled amounts due from medical facilities or independent distributors (the "Customer"). Upon completion of a procedure, we recognize revenue and an unbilled receivable is recorded. Upon receipt of a purchase order from the Customer, 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 from the Customer. 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 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 net realizable 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 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, 2019, and 2018, we recognized provisions of $2.8 million, and $1.9 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.

Goodwill

Goodwill relates to amounts that arose in connection with the acquisition of ImaTx, Inc. in 2009 and the acquisition of BPM in 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 requiring 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 projections 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 as of September 30, 2018.

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. At December 31, 2019, our intangible assets were fully amortized. 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. The cash flow analysis performed for the year-ended December 31, 2019 did not indicate impairment.

In 2019, we recognized $0.1 million in impairment charges related to assets no longer being used. In 2018, we recognized $2.4 million in impairment charges of which $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.

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

Index to Consolidated Financial Statements

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, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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 2, 2020

CONFORMIS, INC. AND SUBSIDIARIES

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

	December 31, 2019	December 31, 2018
Assets		
Current Assets		
Cash and cash equivalents	$ 26,394	$ 16,380
Investments	—	7,245
Accounts receivable, net	11,066	13,244
Royalty receivable	165	145
Inventories	12,074	9,534
Prepaid expenses and other current assets	2,815	1,408
Total current assets	52,514	47,956
Property and equipment, net	13,356	14,439
Operating right-of-use assets	5,853	—
Other Assets		
Restricted cash	462	462
Intangible assets, net	—	109
Other long-term assets	211	17
Total assets	$ 72,396	$ 62,983
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 6,920	$ 3,445
Accrued expenses	7,135	7,930
Operating lease liabilities	1,469	—
Advance on research and development	2,331	—
Total current liabilities	17,855	11,375
Other long-term liabilities	1,500	616
Contract liability	12,000	—
Long-term debt, less debt issuance costs	19,623	14,792
Operating lease liabilities	5,071	—
Total liabilities	56,049	26,783
Commitments and contingencies (Note J)		
Stockholders’ equity		
Preferred stock, $0.00001 par value:		
Authorized: 5,000,000 shares authorized at December 31, 2019 and December 31, 2018; no shares issued and outstanding as of December 31, 2019 and December 31, 2018	—	—
Common stock, $0.00001 par value:		
Authorized: 200,000,000 shares authorized at December 31, 2019 and December 31, 2018; 70,427,400 and 65,290,879 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	1	1
Additional paid-in capital	521,356	513,336
Accumulated deficit	(504,145)	(475,667)
Accumulated other comprehensive loss	(865)	(1,470)
Total stockholders’ equity	16,347	36,200
Total liabilities and stockholders’ equity	$ 72,396	$ 62,983

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,	
	2019	2018
Revenue		
Product	$ 76,649	$ 78,627
Royalty	780	11,162
Total revenue	77,429	89,789
Cost of revenue	40,692	41,304
Gross profit	36,737	48,485
Operating expenses		
Sales and marketing	28,514	38,955
Research and development	12,457	16,869
General and administrative	20,895	24,622
Goodwill impairment	—	6,731
Total operating expenses	61,866	87,177
Loss from operations	(25,129)	(38,692)
Other income and expenses		
Interest income	330	659
Interest expense	(2,942)	(3,356)
Foreign currency transaction loss	(692)	(1,915)
Total other expenses, net	(3,304)	(4,612)
Loss before income taxes	(28,433)	(43,304)
Income tax provision	45	61
Net loss	$ (28,478)	$ (43,365)
Net loss per share - basic and diluted	$ (0.44)	$ (0.74)
Weighted average common shares outstanding - basic and diluted	64,122,455	58,886,333

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,	
	2019	2018
Net loss	$ (28,478)	$ (43,365)
Other comprehensive income		
Foreign currency translation adjustments	605	1,733
Change in unrealized gain on available-for-sale securities, net of tax	—	33
Comprehensive loss	$ (27,873)	$ (41,599)

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, 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
Issuance of common stock—option exercise	81,441	—	184			184
Issuance of common stock—restricted stock	3,195,097	—	—			—
Issuance of common stock— ATM offering	1,084,789	—	1,999			1,999
Issuance of common stock— Innovatus Investment	775,194	—	3,000			3,000
Compensation expense related to issued stock options and restricted stock awards			2,837			2,837
Net loss				(28,478)		(28,478)
Other comprehensive income					605	605
Balance, December 31, 2019	70,427,400	$ 1	$ 521,356	$ (504,145)	$ (865)	$ 16,347

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,	
	2019	2018
Cash flows from operating activities		
Net loss	$ (28,478)	$ (43,365)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization expense	4,237	4,122
Stock-based compensation expense	2,837	3,886
Unrealized foreign exchange loss, net	606	1,806
Non-cash lease expense	1,146	—
Provision for bad debts on trade receivables	106	(72)
Impairment of goodwill	—	6,731
Impairment of long-term assets	69	2,433
Disposal of long-term assets	(200)	(4)
Loss on extinguishment of debt	1,085	—
Non-cash interest expense	423	125
Accretion on investments	(4)	(18)
Deferred tax	—	(37)
Changes in operating assets and liabilities:		
Accounts receivable	2,070	28
Royalty receivable	(20)	55
Inventories	(2,539)	(350)
Prepaid expenses and other assets	(1,623)	529
Accounts payable, accrued expenses, and other liabilities	1,615	(1,045)
Contract liability	12,000	—
Advance on research and development	3,832	—
Net cash used in operating activities	(2,838)	(25,176)
Cash flows from investing activities:		
Acquisition of property and equipment	(2,926)	(4,059)
Purchase of investments	—	(27,430)
Maturity of investments	7,250	47,115
Net cash provided by investing activities	4,324	15,626
Cash flows from financing activities:		
Proceeds from exercise of common stock options	184	112
Debt issuance costs	(737)	—
Loss on extinguishment of debt	(919)	—
Proceeds from issuance of debt	20,000	—
Payments on long-term debt	(15,000)	(15,000)
Debt prepayment fee	—	(225)
Net proceeds from issuance of common stock	4,999	22,768
Net cash provided by financing activities	8,527	7,655
Foreign exchange effect on cash and cash equivalents	1	(73)
Increase/(decrease) in cash, cash equivalents, and restricted cash	10,014	(1,968)
Cash, cash equivalents, and restricted cash beginning of period	16,842	18,810
Cash, cash equivalents, and restricted cash end of period	$ 26,856	$ 16,842
Supplemental information:		
Cash paid for interest	2,123	2,837
Non cash investing and financing activities		
Issuance of common stock for equity financing	—	77

The accompanying notes are an integral part of these 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 personalized, 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 personalized 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. 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 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, 2019, the Company had an accumulated deficit of $504.1 million.

At December 31, 2019, the Company had cash and cash equivalents and investments of $26.4 million and $0.5 million in restricted cash allocated to a lease deposit.

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., ("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, 2019, the Company has sold 1,870,069 Shares under the Distribution Agreement resulting in net proceeds of $3.6 million.

On December 17, 2018, the Company entered into a stock purchase agreement with Lincoln Park Capital ("LPC" and the "LPC Agreement"). Upon entering the LPC Agreement, 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. Additionally, as consideration for LPC’s commitment to purchase shares of common stock under the LPC Agreement, 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 not to exceed 12,297,210 shares over a 36-month period subject to the terms of the LPC Agreement. 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 Agreement, 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 Agreement, 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 Agreement) is below a floor price of

$0.25 per share. No warrants, derivatives, financial or business covenants are associated with the LPC Agreement 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 Agreement may be terminated by the Company at any time, at its sole discretion, without any cost or penalty. As of December 31, 2019, the Company has sold 2,276,398 Shares under the LPC Agreement resulting in net proceeds of $1.0 million.

On June 25, 2019, the Company entered into a Loan and Security Agreement (the "2019 Secured Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP ("Innovatus"), as collateral agent and lender, East West Bank and the other lenders party thereto from time to time (collectively, the "Lenders"), pursuant to which the Lenders agreed to make term loans and revolving credit facility to the Company to repay existing indebtedness, for working capital and general business purposes, in a principal amount of up to $30 million. The Company used the proceeds from the debt financings to pay off its senior secured loan and security agreement (the "2017 Secured Loan Agreement") with Oxford Finance LLC ("Oxford"). In addition, Innovatus purchased approximately $3 million of the Company's common stock at the previous day's closing price. For further information regarding the 2017 Secured Loan Agreement and the 2019 Secured Loan Agreement, see “Note K—Debt and Notes Payable” in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

On September 30, 2019, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Howmedica Osteonics Corp., a subsidiary of Stryker Corporation also known as Stryker Orthopaedics ("Stryker"). In connection with entering into the Asset Purchase Agreement, the Company and Stryker also entered into a Development Agreement (the "Development Agreement"), a License Agreement (the "License Agreement"), a Distribution Agreement (the "Distribution Agreement"). and, together with the Asset Purchase Agreement, the Development Agreement and the License Agreement, the "Agreements") and other ancillary agreements contemplated by the Agreements. Under the terms of the agreements, the Company agreed to sell and license to Stryker certain assets relating to the Company's patient-specific instrumentation technology, and to develop, manufacture, and supply patient-specific instrumentation for use in connection with Stryker's "off-the-shelf," non-personalized knee implant offerings. The Company received $14 million upfront and will receive up to an additional $16 million in milestone payments pursuant to the License Agreement and the Development Agreement. As of December 31, 2019, the Company successfully completed the first out of three milestones with Stryker. Under the long-term Distribution Agreement, the Company will supply patient-specific instrumentation to Stryker. The Company may be required to pay back a portion of the initial payment as it is contingent on the successful completion of milestones set forth in the Development Agreement and License Agreement.

The Company expects that its existing cash and cash equivalents as of December 31, 2019, anticipated revenue from operations, the successful completion of the milestones set forth in the Development Agreement and License Agreement, available sales of shares under the Equity Distribution Agreement and LPC Agreement, available borrowings under the revolving credit facility, and revenue that may be generated in connection with licensing its intellectual property will enable the Company to fund operating expenses and capital expenditure requirements and pay debt service as it becomes due for at least the next 12 months from the date of filing. In order for the Company to meet its operating plan beyond this timeframe, gross margin improvements and operating expense reductions will be necessary to reduce cash used in operations, and the Company will need to successfully complete milestones set forth in the Development Agreement and the License Agreement. When the Company needs additional equity or debt financing proceeds to fund its operations after the next 12 months from the date of filing, 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 ongoing basis, the Company validates alternate suppliers relative to certain key components as needed.

For the years ended December 31, 2019 and 2018, 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, 2019 and 2018.

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, money market funds, treasury bonds, corporate bonds and commercial paper 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 funds 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 $0.8 million as of December 31, 2019 and $1.1 million as of December 31, 2018 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, 2019 and 2018. Restricted cash consisted of security provided for lease obligations.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows.

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 26,394	$ 16,380
Restricted cash	462	462
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 26,856	$ 16,842

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 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 or independent distributors (the "Customer"). Upon completion of a procedure, 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 from the Customer, 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 orders 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, 2019 and 2018, the Company recognized provisions of $2.8 million and $1.9 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.

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 that 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 projections 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 as of September 30, 2018.

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. At our annual impairment review on December 31, 2019, the cash flow analysis performed did not indicate impairment.

In 2019, the Company specifically identified long-lived assets that have become impaired and recorded $0.1 million in 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 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 relate primarily to the discontinuance of software applications. Impairment charges are included in General and administrative expense.

Leases

The Company adopted ASU No. 2016-02-Leases ("Topic 842" or "ASC 842"), as of January 1, 2019, in accordance with ASU 2018-11-Leases (Topic 842) ("ASU 2018-11"), issued by the FASB in July 2018. ASU 2018-11 allows an entity to elect not to recast its comparative periods in the period of adoption when transitioning to ASC 842 (the “Comparatives Under 840 Option”). Effectively, an entity would be permitted to change its date of initial application to the beginning of the period of adoption of ASC 842. In doing so, the entity would apply ASC 840 in the comparative periods and provide the disclosures required by ASC 840 for all periods that continue to be presented in accordance with ASC 840. Further, the entity would recognize the effects of applying ASC 842 as a cumulative-effect adjustment to retained earnings as of the effective date. Under the Comparatives Under 840 Option, this date would represent the date of initial application. The Company is not required to restate comparative periods for the effects of applying ASC 842, provide the disclosures required by ASC 842 for the comparative periods, nor change how the transition requirements apply, only when the transition requirements apply. The Company elected to report

results for periods after January 1, 2019 under ASC 842 and prior period amounts are reported in accordance with ASC 840.

The Company has elected not to separate non-lease components from all classes of leases. Non-lease components have been accounted for as part of the single lease component to which they are related.

Leases with an initial term of 12 months or less are not recorded on the balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

Adoption of the new standard resulted in the recording of additional right-of-use assets and lease liabilities of $7.0 million and $7.7 million, respectively, as of January 1, 2019. The difference between the additional lease assets and lease liabilities is related to deferred rent, which was previously recorded as deferred rent within Accrued expenses and Other long-term liabilities under ASC 840. The adoption of the standard did not impact the Company's consolidated net earnings and had no impact on cash flows.

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, 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.

Product 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, 2019. 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.

Unconditional rights to consideration are reported as receivables. Incidental items that are immaterial in the context of the contract are recognized as expense. At December 31, 2019 and 2018, the Company did not have contract assets or liabilities recorded on the Consolidated Balance Sheets derived from product revenue.

Royalty Revenue Recognition

The Company receives ongoing sales-based royalty from MicroPort. Royalty revenue is recorded at the expected value of the royalty revenue.

On September 30, 2019 the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Howmedica Osteonics Corp., a subsidiary of Stryker Corporation also known as Stryker Orthopaedics ("Stryker"). In connection with entering into the Asset Purchase Agreement, the Company and Stryker also entered into a Development Agreement (the "Development Agreement"), a License Agreement (the "License Agreement"), a Distribution Agreement (the "Distribution Agreement". and, together with the Asset Purchase Agreement, the Development Agreement and the License Agreement, the "Agreements") and other ancillary agreements contemplated by the Agreements. Under the terms of the agreements, the Company agreed to sell and license to Stryker certain assets relating to the Company's patient-specific instrumentation technology, and to develop, manufacture, and supply patient-specific instrumentation for use in connection with Stryker's "off-the-shelf," non-personalized knee implant offerings. The Company received $14 million upfront and will receive up to an additional $16 million in milestone payments pursuant to the License Agreement and the Development Agreement. Under the long-term Distribution Agreement, the Company will supply patient-specific instrumentation to Stryker. The Agreements contain termination provisions whereas under certain circumstances, Stryker may be able to terminate the Development Agreement and a portion of the initial payment is repaid to Stryker. Conversely, under certain circumstances, Stryker could terminate and pay an additional fee for the right to use the Company's intellectual property to sell patient specific-instrumentation with their off-the-shelf knee offering, subject to a sales-based royalty fee.

The Company determined that the Asset Purchase Agreement and the License Agreement are within the scope of ASC 606. Under the Asset Purchase and License Agreements, the Company is required to provide certain assets and the right to use the license for a specific purpose. The assets and the right to use the license are highly interdependent and is considered one performance obligation. The Company bifurcated the total transaction price of $30.0 million into two components; $5.0 million related to cost reimbursement for other services (development) and $25.0 million allocated to royalty revenue determined using the residual approach by deducting the cost reimbursement component from the total transaction price. The arrangement does not contain a significant financing component.

The Company records a contract liability when there is an obligation to transfer goods or services to a customer for which the Company has received consideration from the customer. At December 31, 2019 the Company recorded $12.0 million as a long-term contract liability related to consideration received from the customer under the Asset Purchase and Development Agreements. The Company concluded the license rights under the License Agreement is functional when FDA 510(k) clearance is received as required under Milestone 3 in the License Agreement, or upon termination by Stryker and Stryker's election to purchase the license rights.

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 years ended December 31, 2019 and 2018 (in thousands):

	Years Ended December 31,	
	2019	2018
Beginning Balance	$ 96	$ 119
Provision related to current period sales	145	129
Adjustment related to prior period sales	20	40
Payments or credits issued to customer	(134)	(192)
Ending Balance	$ 127	$ 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 $1.8 million and $1.6 million for the years ended December 31, 2019 and 2018, 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.

Collaborative arrangements

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, *Collaborative Arrangements* (ASC 808). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently. Amounts that are received from collaboration are recognized as an offset to Research and development expense when incurred.

Under the Development Agreement with Stryker, the Company has three milestone deliverables in which the Company must deliver the first prototype of the patient-specific instrumentation (referred to as "PSI") to be used

with Stryker's off-the-shelf knee implant, design freeze of the PSI, and FDA 510(k) submission of the developed product. In December 2019, the Company met the first milestone under the Development Agreement.

For the year ended December 31, 2019, the Company recognized $0.2 million in Research and development expense, offset by a portion of the advance on development received upon execution of the agreements. The remaining portion of the advance of $2.3 million is classified as a short-term Advance on research and development on the Consolidated Balance Sheets and will be used to offset future expenses incurred under the Development Agreement. Upon successful completion of milestone 1 in December 2019, the Company recorded an additional advance on research and development of $1.5 million within Other long-term liabilities on the Consolidated Balance Sheets.

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 $0.5 million and $0.7 million for the years ended December 31, 2019 and 2018, respectively.

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 personalized joint replacement products and that the Company operates as one segment. See "Note O—Segment and Geographic Data."

Comprehensive loss

At December 31, 2019 and 2018, accumulated other comprehensive loss consists of foreign currency translation adjustments. The following table summarizes accumulated beginning and ending balances of foreign currency translation adjustments in Accumulated other comprehensive 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)
Change in period	605	—	605
Balance December 31, 2019	$ (865)	$ —	$ (865)

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. 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, 2019 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.

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 fair value for restricted stock awards and performance awards is the grant date close price of the Company's Common

Stock as reported by NASDAQ. 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)	**2019**	**2018**
Numerator:		
Numerator for basic and diluted loss per share:		
Net loss	$ (28,478)	$ (43,365)
Denominator:		
Denominator for basic loss per share:		
Weighted average shares	64,122,455	58,886,333
Basic loss per share attributable to Conformis, Inc. stockholders	$ (0.44)	$ (0.74)
Diluted loss per share attributable to Conformis, Inc. stockholders	$ (0.44)	$ (0.74)

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,	
	2019	**2018**
Common stock warrants	—	—
Stock options, restricted stock awards, performance awards	2,992,120	55,346
Total	2,992,120	55,346

Recent accounting pronouncements

In December 2019, the FASB issued ASU No. 2019-12, "Simplifying the Accounting for Income Taxes." This ASU amends Topic 740 Income Taxes in an effort to reduce the complexity of accounting for hybrid tax regimes, tax basis step-up in goodwill obtained in a transaction that is not a business combination, separate financial statements of legal entities not subject to tax, intraperiod tax allocation exception to incremental approach, ownership changes in investments, and year-to-date loss limitation in interim-period tax accounting. The ASU is effective for fiscal years beginning after December 15, 2020, including interim periods therein. Early adoption is permitted. The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements.

In July 2019, the FASB issued ASU No. 2019-07, "Amendments to SEC Paragraphs Pursuant to SEC Final Rule Releases No. 33-10532, Disclosure Update and Simplification, and Nos. 33-10231 and 33-10442, Investment Company Reporting Modernization, and Miscellaneous Updates." This ASU updates the codification to reflect the amendments of various SEC disclosure requirements. The ASU became effective on July 26, 2019 and did not have an impact on our consolidated financial statements.

In April 2019, the FASB issued ASU No. 2019-04, "Codification Improvements to Topic 326, Financial Instruments - Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments." This ASU clarifies and answers questions related to ASU No. 2018-13 and ASU No. 2016-13 and has the same effective dates of the respective pronouncements described below.

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 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. In May 2019, the FASB issued ASU No. 2019-13, "Financial Instruments - Credit Losses (Topic 326) Targeted Transition Relief," which allows for a transition election on certain instruments. The guidance is effective for Small Reporting Companies for fiscal years beginning after December 15, 2022 and interim periods in those fiscal years. In November 2019, the FASB issued ASU No. 2019-11 which amends certain aspects of ASU No. 2019-13, including transition relief for trouble debt restructuring, among other topics. The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements.

Correction of an Immaterial Error

Certain amounts disclosed in the prior period have been corrected. In the Consolidated Statement of Cash Flows for the year ended December 31, 2018, the Company corrected the cash flow presentation of unrealized foreign currency transaction gains or losses of $1.8 million resulting from changes in exchange rates between the functional currency and the currency in which a foreign currency transaction is denominated to reflect such cash flows as non-cash adjustment to cash flows from operating activities.

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 Company did not have any assets measured at fair value at December 31, 2019. 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 equivalents	Short-term (1) investments
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	$ 13,788	$ —	$ —	$ 13,788	$ 6,543	$ 7,245

(1) Contractual maturity due within one year.

Note D—Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Total receivables	$ 11,401	$ 13,634
Allowance for doubtful accounts and returns	(335)	(390)
Accounts receivable, net	$ 11,066	$ 13,244

The beginning accounts receivable balance as of January 1, 2018 was $13.2 million. All activity within accounts receivables relate to normal operational activity from the period. Accounts receivable included unbilled receivable of $2.1 million and $2.2 million for the years ended December 31, 2019 and 2018. Write-offs related to accounts receivable were approximately $187,000, $115,000, for the years ended December 31, 2019 and 2018, respectively.

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

	December 31, 2019	December 31, 2018
Beginning balance	$ (390)	$ (635)
Provision for bad debts on trade receivables	(106)	72
Other allowances	(26)	58
Accounts receivable write-offs	187	115
Ending balance	$ (335)	$ (390)

Note E—Inventories

Inventories consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Raw Material	$ 6,171	$ 4,498
Work in process	1,717	1,518
Finished goods	4,186	3,518
Total Inventories	$ 12,074	$ 9,534

Note F—Property and Equipment

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

	Estimated Useful Life (Years)	December 31, 2019	December 31, 2018
Equipment	5-7	$ 19,011	$ 18,602
Furniture and fixtures	5-7	864	954
Computer and software	3	9,561	8,783
Leasehold improvements	3-7	2,008	1,978
Reusable instruments	5	3,402	1,573
Total property and equipment		34,846	31,890
Accumulated depreciation		(21,490)	(17,451)
Property and equipment, net		$ 13,356	$ 14,439

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 $4.1 million and $4.0 million for the years ended December 31, 2019 and 2018, respectively. In 2019, the Company recognized $0.1 million in impairment charges. In 2018, the Company incurred $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 relate primarily to the discontinuance of software applications.

Note G—Intangible Assets

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

	Estimated Useful Life (Years)	December 31, 2019	December 31, 2018
Developed technology	10	$ 979	$ 979
Accumulated amortization		(979)	(881)
Developed technology, net		—	98
Acquired favorable lease	5	—	15
Accumulated amortization		—	(4)
Acquired favorable lease, net		—	11
Intangible assets, net		$ —	$ 109

The Company recognized amortization expense of $0.1 million in the years ended December 31, 2019 and 2018. The Company's intangible asset was fully amortized as of December 31, 2019.

Note H—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Accrued employee compensation	$ 3,198	$ 3,138
Deferred rent	—	132
Accrued legal expense	310	215
Accrued consulting expense	21	84
Accrued vendor charges	1,037	1,441
Accrued revenue share expense	1,050	1,134
Accrued clinical trial expense	394	549
Accrued other	1,125	1,237
	$ 7,135	$ 7,930

Note I—Leases

The Company adopted Topic 842 as of January 1, 2019. Refer to "Note B—Summary of Significant Accounting Policies" for the impact of adoption on the Company's Consolidated Financial Statements.

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

The Company's leases have remaining lease terms of approximately one-to-six years, some of which include one or more options to extend the leases for up to five years per renewal. The exercise of lease renewal options is at the sole discretion of the Company. The amounts disclosed in the Consolidated Balance Sheet pertaining to right-of-use assets and lease liabilities are measured based on management's current expectations of exercising its available renewal options.

The Company's existing leases are not subject to any restrictions or covenants which preclude its ability to pay dividends, obtain financing, or enter into additional leases.

As of December 31, 2019 the Company has not entered into any leases which have not yet commenced which would entitle the Company to significant rights or create additional obligations.

The Company uses either its incremental borrowing rate or the implicit rate in the lease agreement as the basis to calculate the present value of future lease payments at lease commencement. The incremental borrowing rate represents the rate the Company would have to pay to borrow funds on a collateralized basis over a similar term and in a similar economic environment.

Cash paid for amounts included in lease liability was $1.7 million for the year-ended December 31, 2019. The components of lease expense and related cash flows were as follows (in thousands):

	December 31, 2019	December 31, 2018
Rent expense	$ 1,526	$ 1,511
Variable lease cost (1)	378	—
	$ 1,904	$ 1,511

(1) Variable operating lease expenses consist primarily common area maintenance and real estate taxes for the year ended months ended December 31, 2019.

Deferred rent was $0.7 million as of December 31, 2018. Deferred rent is included in accrued expenses and other long-term liabilities.

As of December 31, 2019, the remaining weighted-average lease term of the operating leases was 5.02 years and the weighted-average discount rate was 6.0%.

The future minimum rental payments under these agreements as of December 31, 2019 were as follows (in thousands):

Year	Minimum Lease Payments
2020	$ 1,615
2021	1,633
2022	1,399
2023	1,053
After 2023	1,885
Total lease payments	$ 7,585
Present value adjustment	(1,045)
Present value of lease liabilities	$ 6,540

Note J—Commitments and Contingencies

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 personalized 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 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. The Company incurred revenue share expense for Dr. Lang of $0.7 million for the year ended December 31, 2018. Dr. Lang was not a related party in 2019.

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 $2.0 million during the year ended December 31, 2019, representing 2.6% of product revenue and $3.1 million during the year ended December 31,

2018, representing 4.0% 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, 2019 (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)	$ 1,541	$ 432	$ 359	$ 300	$ 450

(1) Represents amounts payable under our product royalty agreement, operating leases for office equipment, 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, 2019 or December 31, 2018.

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 August 15, 2019, the Company filed a lawsuit against Zimmer Biomet Holdings, Inc. and Zimmer, Inc., “Zimmer Biomet”, in the United States District Court for the District of Delaware seeking damages for Zimmer Biomet’s infringement of certain of the Company’s patents related to patient-specific instrument and implant systems. The complaint alleges that Zimmer Biomet’s multiple lines of patient-specific instruments, as well as the implant components used in conjunction with them, infringe four of our patents. The accused product lines include Zimmer Biomet patient-specific instrument and implant systems for knee, shoulder, and hip replacement procedures. On November 5, 2019, Zimmer Biomet filed a lawsuit against the Company in the United States District Court for the District of Delaware, alleging that we infringe five patents owned by Zimmer Biomet. Zimmer Biomet alleges that our iTotal CR and iTotal PS products infringe all five asserted patents, that our iDuo product infringes three of the asserted patents, and that our iUni product infringes two of the asserted patents. On January 13, 2020, Zimmer Biomet filed a motion to dismiss our complaint, and we filed our answer to Zimmer Biomet's complaint, denying that the Company's products infringe Zimmer Biomet’s asserted patents. The Company's answer also alleges that Zimmer Biomet’s asserted patents are invalid.

On August 29, 2019, the Company filed a lawsuit against Medacta USA, Inc., “Medacta”, in the United States District Court for the District of Delaware, and amended its complaint on December 23, 2019, seeking damages for Medacta’s infringement of certain of our patents related to patient-specific instrument and implant systems. The Company alleges in the lawsuit that Medacta’s multiple lines of patient-specific instruments, as well as the implant components used in conjunction with them, infringe four of our patents. The accused product lines include Medacta patient-specific instrument and implant systems for knee and shoulder replacement procedures. On January 6, 2020, Medacta filed its answer, denying that its patient-specific instrument and implant systems infringe the patents asserted by the Company. Medacta’s answer also alleges the affirmative defense that our asserted patents are invalid.

An adverse outcome of these lawsuits could have a material adverse effect on our business, financial condition or results of operations. The Company is presently unable to predict the outcome of these lawsuits or to reasonably estimate a range of potential losses, if any, related to the lawsuits.

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, 2019	December 31, 2018
Term A Loan	$ —	$ 7,500
Term B Loan	—	7,500
Innovatus, Term Loan	20,000	—
	20,000	15,000
Innovatus, Term Loan accrued payment-in-kind interest	262	—
Less unamortized debt issuance costs	(639)	(208)
Long-term debt, less debt issuance costs	$ 19,623	$ 14,792

Principal payments due as of December 31, 2019 consisted of the following (in thousands):

	Principal Payment
2020	$ —
2021	—
2022	—
2023	8,986
2024	12,580
Total	$ 21,566

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 were reduced to $5 million.

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.

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.

On June 25, 2019, the Company elected to prepay the remainder of the Oxford term loan outstanding (along with accrued interest and applicable final payment and prepayment fee) using the proceeds from the 2019 Secured Loan Agreement. The prepayment of the debt was accounted for as a debt extinguishment and the Company incurred a loss on the extinguishment recognized in Interest expense of $1.1 million.

2019 Secured Loan Agreement

On June 25, 2019, the Company entered into the 2019 Secured Loan Agreement with Innovatus, as collateral agent and lender, East West Bank and the Lenders, pursuant to which the Lenders agreed to make term loans and revolving credit facility to the Company to repay existing indebtedness, for working capital and general business purposes, in a principal amount of up to $30 million.

The term loan facility established under the 2019 Secured Loan Agreement is secured by substantially all of the Company's and its U.S. subsidiaries' properties, rights and assets.

The 2019 Secured Loan Agreement includes a trailing six months' revenue test, a liquidity covenant and an additional liquidity covenant that is applicable if there are borrowings under the revolving credit facility. The 2019 Secured Loan Agreement also includes customary representations, affirmative and negative covenants. Additionally, the 2019 Secured Loan Agreement 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 Innovatus, as collateral agent, with the right to accelerate all obligations under the 2019 Secured Loan Agreement and to exercise remedies against the Company and the collateral securing the credit facility, including foreclosure against assets securing the credit facilities, including the Company's cash. These events of default include, among other things, the Company's failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, the Company's insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $250,000, one or more judgments against the Company in an amount greater than $500,000, changes with respect to governmental approvals and FDA actions.

As of December 31, 2019, the Company was in compliance of covenants under the 2019 Secured Loan Agreement.

Term Loan - Innovatus

The term loan under the 2019 Secured Loan Agreement bears interest at a floating annual rate calculated at the greater of the variable rate of interest as most recently announced by East West Bank as prime or 5.50%, plus 3.75% ("Term Loan Basic Interest Rate"), bearing an effective interest rate of 9.25% at December 31, 2019. The Company is required to make interest only payments in arrears on the term loan for four years; provided that the Company has elected to pay 2.50% per annum as such Term Loan Basic Interest Rate in-kind by adding an amount equal to 2.50% per annum of the outstanding principal amount to the then outstanding principal balance on a monthly basis until the third anniversary of the 2019 Secured Loan Agreement. Commencing July 1, 2023, and continuing on the payment date of each month thereafter, the Company is required to make consecutive equal monthly payments of principal of the term loan, together with accrued interest, in arrears, to the Lenders. All unpaid principal, accrued and unpaid interest with respect to the term loan, and a final fee in the amount of 5.0% of the term loan commitment, is due and payable in full on the term loan maturity date on June 1, 2024.

At the Company's option, the Company may prepay all, but not less than all, of the term loans advanced by the Lenders under the term loan facility after the first year, 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 fee, plus all other amounts that are due and payable, including the Lenders' expenses and interest at the default rate with respect to any past due amounts.

Revolving Credit Facility - East West Bank

Under the 2019 Secured Loan Agreement, East West Bank will make loans of up to $10 million from time to time outstanding, subject to availability based on a borrowing base equal to (i) 85.00% of eligible customer accounts, subject to a maximum of 2.50% dilution based upon collections, minus (ii) the Company's foreign accounts receivable credit insurance's outstanding co-payment and minimum annual deductible (that has not been used at the applicable time). Advances under the revolving credit facility bear interest at a rate of 0.50% above the greater of East West Bank's prime rate or 5.50%. Interest on the revolving advances is payable monthly in arrears. The revolving credit facility terminates and the principal and all amounts are due in full on June 25, 2024, provided that if an optional or mandatory prepayment (other than regularly scheduled payments) is made under the term loan, the Company must satisfy in full the obligations under the revolving credit line. The revolving credit facility requires a lockbox arrangement, which provides for all receipts to be swept daily to reduce the borrowings outstanding under the revolving credit facility.

There were no amounts outstanding under the revolving credit facility at December 31, 2019.

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 in expenses in connection with the filing and prosecution of the patent applications licensed to the Company by Vertegen for the year ended December 31, 2018.

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.

During 2018, Dr. Lang ceased being a related party, therefore due to the association with Dr. Lang, Vertegen is no longer a related party to the Company.

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 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 for the year ended December 31, 2018. Dr. Lang is not considered a related party in 2019.

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.

In conjunction with the 2019 Secured Loan Agreement, on June 25, 2019, the Company entered into an investment agreement (the "Investment Agreement"), with Innovatus, Innovatus Life Science Offshore Fund I, LP and Innovatus Life Sciences Offshore Fund I-A, LP (collectively, the "Innovatus Investors"), pursuant to with the Company agreed to issue and sell to the Innovatus Investors an aggregate of 775,194 shares of shares of the Company's common stock, par value $0.00001 per share (the "Shares"), in a private placement (the "Private Placement"). The Investors paid $3.87 per share. The Private Placement closed on June 25, 2019. The Company received aggregate gross proceeds from the Private Placement of approximately $3.0 million before deducting expenses associated with the transaction. The Company has granted the Investors specified indemnification rights with respect to its representations, warranties, covenants and agreements under the Investment Agreement.

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, 2019 and December 31, 2018.

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. Under the Registration Rights Agreement, the registration rights expired on July 7, 2019.

In conjunction with the Private Placement, on June 25, 2019, the Company entered into a registration rights agreement (the "2019 Registration Rights Agreement"), with the Innovatus Investors, pursuant to which the Company agreed to register for resale the Shares held by the Investors under certain circumstances. Under the Registration Rights Agreement, in the event that the Company receives a written request from the Innovatus Investors that the Company file with the U.S. Securities and Exchange Commission (the "SEC") a registration statement covering the resale of all of the Shares, the Company shall promptly but no later than 120 days after the date of such request prepare and file with the SEC such registration statement. The Innovatus Investors have agreed to use best efforts not to make such a request, including by effecting any planned sales of Shares under Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"). The Company has agreed to use commercially reasonable efforts to cause such registration statement to become effective and to keep such registration statement effective until the date the Shares covered by such registration statement have been sold or may be resold pursuant to Rule 144 without restriction. The Company has agreed to be responsible for all fees and expenses incurred in connection with the registration of the Shares. The Company has granted the Innovatus

Investors customary indemnification rights in connection with the registration statement. The Innovatus Investors have also granted the Company customary indemnification rights in connection with the registration statement.

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, 2019 and 2018. 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, 2019 and December 31, 2018. 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, 2018	28,926	$ 9.80	28,926	$ 9.80	4.66
Outstanding December 31, 2019	28,926	$ 9.80	28,926	$ 9.80	3.66

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, 2019, 1,328,752 shares of common stock were available for future issuance under the 2015 Plan.

On April 29, 2019, the stockholders approved the Conformis, Inc. 2019 Sales Team Performance-Based Equity Incentive Plan ("2019 Sales Team Plan") for up to 3,000,000 shares of common stock available to grant to certain sales representatives or independent sales agents. The 2019 Sales Team Plan provides for the grant of performance-based equity, including incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. Shares covered by awards under the 2019 Sales Team Plan that expire or are terminated, surrendered, or cancelled without having been fully exercised or are forfeited in whole or in part (including as the result of shares subject to such award being repurchased by us at the original issuance price pursuant to a contractual repurchase right) or that result in any shares not being issued, will again be available for the grant of awards under the 2019 Sales Team Plan. Equity granted under the 2019 Sales Team Plan will expire ten years from the date of the grant. As of December 31, 2019, no shares of common stock were issued or outstanding under the 2019 Sales Team Plan.

Stock option activity under all stock plans was as follows:

	Number of Options	Weighted Average Exercise Price per Share	Aggregate Intrinsic Value (In Thousands)
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	$ —
Granted	58,553	2.70	
Exercised	(81,441)	2.27	58
Expired	(917,541)	6.94	
Cancelled/Forfeited	(133,307)	2.46	
Outstanding December 31, 2019	1,802,463	$ 6.75	$ 3
Total vested and exercisable	1,548,252	$ 7.05	$ 1

The total fair value of stock options that vested during the year ended December 31, 2019 was $0.6 million. The weighted average remaining contractual term for the total stock options outstanding was 4.01 years at December 31, 2019. The weighted average remaining contractual term for the total stock options vested and exercisable was 3.38 years at December 31, 2019.

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

	Number of Shares	Weighted Average Fair Value
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
Granted	4,405,424	1.09
Vested	(1,231,541)	2.14
Forfeited	(1,210,327)	1.15
Unvested December 31, 2019	4,436,928	$ 1.54

The total fair value of restricted common stock awards that vested during the year ended December 31, 2019 was $2.6 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 fair value for restricted stock awards and performance awards is the grant date close price of the Company's Common Stock as reported by NASDAQ.

The weighted average fair value of options granted was $1.44 and $0.73 for the year ended December 31, 2019 and 2018, respectively.

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,	
	2019	2018
Risk-free interest rate	1.89%	2.75% - 2.90%
Expected term (in years)	6.00	6.25
Dividend yield	—%	—%
Expected volatility	55.80%	53.00% - 56.00%

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 date 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 $2.8 million and $3.9 million for the years ended December 31, 2019 and 2018, 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,	
	2019	2018
Cost of revenue	$ 350	$ 333
Sales and marketing	213	501
Research and development	565	1,029
General and administrative	1,709	2,023
	$ 2,837	$ 3,886

At December 31, 2019, the Company had $0.6 million of total unrecognized compensation expense for options that will be recognized over a weighted average period of 1.60 years. At December 31, 2019, the Company had $5.0 million of total unrecognized compensation expense for restricted awards recognized over a weighted average period of 2.23 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. For financial reporting purposes, loss before income taxes for the years ended December 31, 2019 and 2018 includes the following components (in thousands):

	Years ended December 31,	
	2019	2018
Loss before income taxes:		
U.S.	$ (25,814)	$ (38,219)
Non-U.S.	(2,619)	(5,085)
	$ (28,433)	$ (43,304)

Significant components of the provision for income taxes for the years ended December 31, 2019 and 2018 were as follows (in thousands):

	Years ended December 31,	
	2019	2018
Current:		
Federal	$ —	$ —
State	11	—
Foreign	34	98
	45	98
Deferred:		
Federal	—	(37)
State	—	—
Foreign	—	—
	—	(37)
Total	$ 45	$ 61

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,	
	2019	2018
Tax at U.S. statutory rate	21.00 %	21.00 %
State taxes, net of federal benefits	10.07	3.48
Permanent items	(9.25)	(1.03)
Tax credit	(3.08)	2.27
Change in valuation allowance	(21.90)	198.36
Foreign rate differential	0.71	1.21
Rate change	(1.05)	0.09
Uncertain tax positions	5.65	(0.22)
NQ Stock option expirations & forfeitures	(2.53)	(1.29)
Federal NOL limitation	—	(196.32)
State NOL limitation	—	(25.72)
Deferred revenue - ASC 606 implementation adjustment	—	(2.49)
Other	0.22	0.52
	(0.16)%	(0.14)%

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,	
	2019	2018
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 16,890	$ 14,097
Foreign net operating loss carryforwards	5,080	2,687
Accrued expenses	249	99
Credits	7,519	6,641
Intangibles	1,355	1,350
Stock compensation expense	1,324	1,917
Lease liability	1,653	187
Other	3,750	2,964
Total deferred tax assets	37,820	29,942
Valuation allowance	(35,347)	(29,120)
Net deferred tax assets	2,473	822
Deferred tax liabilities:		
Fixed assets	(994)	(822)
Right of use asset	(1,479)	—
Net deferred tax liabilities	(2,473)	(822)
Net deferred tax liabilities	$ —	$ —

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 $35.3 million valuation allowance at December 31, 2019 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 $6.2 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, 2019, the Company had approximately $413.7 million of federal net operating loss carryforwards and approximately $235.5 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 $255.9 million as of December 31, 2019. The limitations may reduce the amount of federal and state NOLs and credits of $413.7 million and $235.5 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 $33.0 million as of December 31, 2019, 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 $5.1 million and $6.8 million as of December 31, 2019 and 2018, respectively. Of the total liability at December 31, 2019 and 2018, $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,	
	2019	2018
Unrecognized tax benefits beginning of year	$ 6,764	$ 5,136
Gross change for current year positions	836	1,628
Decrease due to statute limitations	(2,482)	—
Unrecognized tax benefits end of the year	$ 5,118	$ 6,764

As of December 31, 2019, 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 cannot be challenged by the German Tax Authorities.

At December 31, 2019, 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.

Note O—Segment and Geographic Data

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,	
	2019	2018
Product Revenue		
United States	$ 67,151	$ 68,062
Germany	7,598	9,007
Rest of World	1,900	1,563
	$ 76,649	$ 78,627

	December 31,	
	2019	2018
Property and equipment, net		
United States	$ 13,303	$ 14,367
Rest of World	53	72
	$ 13,356	$ 14,439

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 $425,000 and $561,000 to the plan during the years ended December 31, 2019 and 2018, respectively.

Note Q —Selected Quarterly Financial Information (Unaudited)

	Three Months Ended			
(in thousands, except per share data)	December 31, 2019	September 30, 2019	June 30, 2019	March 31, 2019
Total revenue	$ 19,889	$ 17,303	$ 19,593	$ 20,644
Gross profit	9,656	7,628	9,622	9,831
Net loss	(5,433)	(8,701)	(6,763)	(7,581)
Net loss per share - basic and diluted	$ (0.08)	$ (0.13)	$ (0.11)	$ (0.12)

	Three Months Ended			
(in thousands, except per share data)	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)

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, 2019. 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, 2019, 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, 2019. 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, 2019, 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 quarter ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On February 4, 2020, we entered into a fifth amendment to the amended and restated employment agreement with Mark Augusti, our Chief Executive Officer, (the “Augusti Amendment”). The Augusti Amendment provides for a bonus award of up to 85% of Mr. Augusti’s base salary effective with fiscal year beginning January 1, 2020.

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 2020 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 2020 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 2020 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 2020 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 2020 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 2020 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 2020 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 2020 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

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
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)
4.2*	Description of securities
10.1^	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)
10.2^	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)
10.3^	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)
10.4^	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)
10.5^	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)
10.6^	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)
10.7^	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)
10.8^	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)
10.9^	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)
10.10^	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)
10.11^	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)
10.12^	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)
10.13^	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)

10.14^	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)
10.15^	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)
10.16^	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)
10.17	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)
10.18	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)
10.19	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)
10.20	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)
10.21†	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)
10.22	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)
10.23	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)
10.24	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)
10.25^	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)
10.26	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)
10.27	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)
10.28	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)

10.29	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)
10.30†	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)
10.31^	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)
10.32	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)
10.33^	Form of 2018 Incentive Compensation Program Award Letter (incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on March 14, 2019)
10.34^	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)
10.35^	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)
10.36^	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)
10.37	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)
10.38†	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)
10.39	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)
10.40	Purchase 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)
10.41	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)
10.42^	Third Amendment to Employment Agreement dated March 8, 2019, by and between Conformis, Inc. and March Augusti, its President and Chief Executive Officer
10.43^	Form of 2019 Incentive Compensation Program Award Letter (incorporated herein by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on March 14, 2019)
10.44^	2019 Sales Team Performance-based Equity Incentive Plan (incorporated by reference to Appendix A to the Registrant's Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934 (File No. 001-37474) filed on March 15, 2019)

10.45	Loan and Security Agreement, dated as of June 25, 2019, by and among Conformis, Inc. and the other parties thereto. (incorporated hereby by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on June 26, 2019)
10.46	Investment Agreement, dated as of June 25, 2019, by and among Conformis, Inc., Innovatus Life Sciences Lending Fund I, LP, Innovatus Life Sciences Offshore Fund I, LP and Innovatus Life Sciences Offshore Fund I-A, LP (incorporated hereby by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on June 26, 2019)
10.47	Registration Rights Agreement, dated as of June 25, 2019, by and among Conformis, Inc., Innovatus Life Sciences Lending Fund I, LP, Innovatus Life Sciences Offshore Fund I, LP and Innovatus Life Sciences Offshore Fund I-A, LP (incorporated hereby by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on June 26, 2019)
10.48^	Employment Agreement dated July 29, 2019, by and between Conformis, Inc. and J. Brent Alldredge, its Chief Legal Officer and Corporate Secretary. (incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 001-37474]) filed on August 2, 2019)
10.49^	Consulting Agreement, effective as of October 19, 2019, by and between Conformis, Inc. and Paul S. Weiner, its former Chief Financial Officer (incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on October 4, 2019)
10.50^*	Offer Letter dated October 14, 2019, by and between Conformis, Inc. and Frederick W.Driscoll, its Interim Chief Financial Officer (incorporated herein by reference to the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on October 21, 2019)
10.51	First Amendment to Loan and Security Agreement, dated as of August 15, 2019, by and among Conformis, Inc. and the other parties thereto (incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q (File No. 001-37474) filed on November 1, 2019)
10.52†	Asset Purchase Agreement, dated as of September 30, 2019, by and between Howmedica Osteonics Corp. and Conformis, Inc. (incorporated herein by reference to Exhibit 10.3 of the Registrant's Form 10-Q (File No. 001-37474) filed on November 1, 2019)
10.53†	Distribution Agreement, dated as of September 30, 2019, by and between Howmedica Osteonics Corp. and Conformis, Inc. (incorporated herein by reference to Exhibit 10.4 of the Registrant's Form 10-Q (File No. 001-37474) filed on November 1, 2019)
10.54†	License Agreement, dated as of September 30, 2019, by and between Howmedica Osteonics Corp. and Conformis, Inc. (incorporated herein by reference to Exhibit 10.5 of the Registrant's Form 10-Q (File No. 001-37474) filed on November 1, 2019)
10.55†	Development Agreement, dated as of September 30, 2019, by and between Howmedica Osteonics Corp. and Conformis, Inc. (incorporated herein by reference to Exhibit 10.6 of the Registrant's Form 10-Q (File No. 001-37474) filed on November 1, 2019)
10.56†	First Amendment to Asset Purchase Agreement, dated as of October 23, 2019, by and between Howmedica Osteonics Corp. and Conformis, Inc. (incorporated herein by reference to Exhibit 10.7 of the Registrant's Form 10-Q (File No. 001-37474) filed on November 1, 2019)
10.57^	Form of 2015 Stock Incentive Plan Performance-Vested Restricted Stock Agreement (incorporated herein by reference to Exhibit 10.8 of the Registrant's Form 10-Q (File No. 001-37474) filed on November 1, 2019)
10.58^	Form of 2019 Sales Team Performance-Based Equity Incentive Plan Performance-Vested Restricted Stock Agreement (incorporated herein by reference to Exhibit 10.9 of the Registrant's Form 10-Q (File No. 001-37474) filed on November 1, 2019)
10.59^*	Fourth Amendment to Amended and Restated Employment Agreement dated November 2, 2019, by and between Conformis, Inc. and Mark Augusti, its Chief Executive Officer
10.60^*	Extension dated December 19, 2019 to Offer Letter dated October 14, 2019, by and between Conformis, Inc. and Frederick W. Driscoll, its Interim Chief Financial Officer
10.61^*	First Amendment to Employment Agreement dated December 23, 2019, by and between Conformis, Inc. and J. Brent Alldredge, its Chief Legal Officer and Corporate Secretary
10.62^*	Form of 2015 Stock Incentive Plan Restricted Stock Grant for Independent Sales Representative

10.63^*	Form of Inducement Restricted Stock Unit Agreement
10.64^*	Form of Inducement Incentive Grant Agreement
10.65^*	Fifth Amendment to Amended and Restated Employment Agreement dated February 4, 2020, by and between Conformis, Inc. and Mark Augusti, its Chief Executive Officer
10.66^	Form of 2020 Incentive Compensation Program Award Letter (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37474) filed on February 5, 2020)
10.67^*	Employment Agreement, effective as of February 17, 2020, by and between Conformis, Inc. and Robert Howe, its Chief Financial Officer
10.68^*	Consulting Agreement, effective as of February 17, 2020, by and between Conformis, Inc. and Frederick W. Driscoll, its former Interim Chief Financial 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: 3/2/2020

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	3/2/2020
/s/Robert Howe Robert Howe	Chief Financial Officer (Principal Financial Officer) and Principal Accounting Officer	3/2/2020
/s/Kenneth Fallon III Kenneth Fallon III	Chairman of the Board of Directors	3/2/2020
/s/Philip W. Johnston Philip W. Johnston	Director	3/2/2020
/s/Carrie Bienkowski Carrie Bienkowski	Director	3/2/2020
/s/Bradley Langdale Bradley Langdale	Director	3/2/2020
/s/Richard Meelia Richard Meelia	Director	3/2/2020
/s/Michael Milligan Michael Milligan	Director	3/2/2020

EXHIBIT 4.2

DESCRIPTION OF SECURITIES REGISTERED UNDER
SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of our common stock, par value $0.00001 per share (the "common stock"), of Conformis, Inc. ("us," "our," "we" or the "Company"), which is the only security of the Company registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), summarizes certain information regarding the common stock in our restated certificate of incorporation, as amended, our amended and restated bylaws and applicable provisions of Delaware corporate law, and is qualified by reference to our restated certificate of incorporation, articles of amendment to restated certificate of incorporation and amended and restated bylaws, which are incorporated by reference as Exhibit 3.1 and, Exhibit 3.2 and Exhibit 3.3, respectively, to the Annual Report on Form 10-K.

Our authorized capital stock consists of 200,000,000 shares of common stock, par value $0.00001 per share, and 5,000,000 shares of preferred stock, par value $0.00001 per share.

Common Stock

Annual Meeting. Annual meetings of our stockholders are held on the date designated in accordance with our bylaws. Written notice must be mailed to each stockholder entitled to vote not less than ten nor more than 60 days before the date of the meeting. The presence in person or by proxy of the holders of record of a majority of our issued and outstanding shares entitled to vote at such meeting constitutes a quorum for the transaction of business at meetings of the stockholders. Special meetings of the stockholders may be called for any purpose by the board of directors, the chairman of the board, or the chief executive officer. Except as may be otherwise provided by applicable law, our certificate of incorporation or our bylaws, all elections shall be decided by a plurality, and all other questions shall be decided by a majority, of the votes cast by stockholders entitled to vote thereon at a duly held meeting of stockholders at which a quorum is present.

Voting Rights. Each holder of common stock is entitled to one vote for each share held on all matters to be voted upon by stockholders.

Dividends. The holders of common stock, after any preferences of holders of any preferred stock, are entitled to receive dividends when and if declared by the board of directors out of legally available funds.

Liquidation and Dissolution. If we are liquidated or dissolved, the holders of the common stock will be entitled to share in our assets available for distribution to stockholders in proportion to the amount of common stock they own. The amount available for common stockholders is calculated after payment of liabilities. Holders of any preferred stock will receive a preferential share of our assets before the holders of the common stock receive any assets.

Other Rights. Holders of the common stock have no right to convert the stock into any other security, have the stock redeemed or purchase additional stock or to maintain their proportionate ownership interest. The common stock does not have cumulative voting rights. Holders of shares of the common stock are not required to make additional capital contributions.

Anti-takeover Effects of our Certificate of Incorporation and Bylaws and Delaware Law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies. In accordance with our certificate of incorporation, our board is divided into three classes serving three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office, even if less than a quorum.

No Written Consent of Stockholders. Our bylaws provide that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting.

Meetings of Stockholders. Our bylaws provide that only a majority of the members of our board of directors then in office, the chairman of the board, or the chief executive officer may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements. Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days or more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. The notice must contain certain information specified in the bylaws. These provisions may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

Amendment to Certificate of Incorporation and Bylaws. As required by the Delaware General Corporation Law, any amendment of our certificate of incorporation must first be approved by a majority of our board of directors and, if required by law or our certificate of incorporation, thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, directors, limitation of liability, exclusive jurisdiction of Delaware Courts and the amendment of our bylaws and certificate of incorporation must be approved by not less than 75% of the outstanding shares entitled to vote on the amendment, and not less than 75% of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least 75% of the outstanding shares entitled to vote on the amendment, or, if the board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Preferred Stock. Our certificate of incorporation provides for 5,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of us or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Section 203 of the Delaware General Corporation Law. We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or

at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Exclusive Jurisdiction of Certain Actions. Our certificate of incorporation requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against our directors, officers and employees for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware, unless we otherwise consent. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

October 14, 2019

Frederick Driscoll
2 Longbranch Ave
Rockport, MA 01966

Re: Offer of employment at Conformis, Inc.

Dear Frederick:

We are very pleased to invite you to join Conformis, Inc., a Delaware corporation (the "***Company***"), as a temporary employee.

1. ***Duties and Responsibilities***. Your assignment will be as Chief Financial Officer – Interim, reporting to Mark Augusti. It is understood and agreed that this assignment is temporary and is scheduled to last no later than December 31, 2019, unless extended by the Company in writing. During your time with the Company, you will be expected to work out of the Company's offices in Billerica, Massachusetts.

2. ***Compensation***. Your initial semi-monthly salary will be $15,000.00, payable in accordance with the Company's customary payroll practice. Your salary is subject to periodic review and adjustment by the Company's Management.

3. ***Confidential Information; Employee Confidential Information, Inventions, Non-Competition, and Non-Solicitation Agreement.*** To enable the Company to safeguard its proprietary and confidential information, it is a condition of employment that you agree to sign the Company's standard form of "Employee Confidential Information, Inventions, Non-Competition, and Non-Solicitation Agreement." A copy of this agreement is enclosed for your review. We understand that you are likely to have signed similar agreements with prior employers, and wish to impress upon you that the Company does not want to receive the confidential or proprietary information of others, and will support you in respecting your lawful obligations to prior employers.

4. ***At-Will Employment***. Should you decide to accept our offer, you will be an "at-will" employee of the Company. This means that either you or the Company may terminate the employment relationship with or without cause at any time. Notwithstanding section 1 above, you understand and agree that your employment may be terminated at any time, including at any time before December 31, 2019.


CONFORMIS

5. ***Authorization to Work***. Federal government regulations require that all prospective employees present documentation verifying their identity and demonstrating that they are authorized to work in the United States. If you have any questions about this requirement, which applies to U.S. citizens and non-U.S. citizens alike, please contact me as soon as possible.

6. ***Complete Offer and Agreement***. This letter contains our complete understanding and agreement regarding the terms of your employment by the Company. There are no other, different or prior agreements or understandings on this or related subjects. Changes to the terms of your employment can be made only in a writing signed by you and an authorized executive of the Company, although it is understood that the Company may, from time to time, in its sole discretion, adjust the salaries to you and its other employees, as well as job titles, locations, duties, responsibilities, assignments and reporting relationships. This offer is extended to you, contingent upon acceptance of information as provided by references, background check and completion of our employment application requested by the Company.

7. ***Start Date; Acceptance of Offer***. We hope that you will accept this offer promptly, and begin your temporary assignment at the Company by Wednesday, October 23, 2019 or a mutually agreeable date. If our offer is acceptable to you, please sign this letter in the space indicated and fax it to my attention at 781-583-5006. This offer expires in three (3) business days. You should be aware that this offer is contingent upon a background check.

Our team was impressed by your accomplishments and potential, and we are enthusiastic at the prospect of your joining us. I look forward to your early acceptance of this offer, and to your contributions to the growth and success of Conformis, Inc.

Sincerely,

/s/ Allison Baker
Allison Baker
Director, Human Resources
Conformis, Inc.

ACCEPTANCE OF EMPLOYMENT OFFER:

I accept the offer of temporary employment by Conformis, Inc. on the terms described in this letter.

Signature: /s/ Frederick W. Driscoll

Date: October 17, 2019

My start date will be: October 23, 2019

FOURTH AMENDMENT TO AMENDED
AND RESTATED EMPLOYMENT AGREEMENT

This Fourth Amendment to Amended and Restated Employment Agreement ("Amendment"), entered into as of November 2, 2019 ("Amendment Effective Date"), is by and between Conformis, Inc. ("Conformis") and Mark A. Augusti ("Executive").

WHEREAS Conformis and Executive are parties to that certain letter agreement of employment dated October 19, 2016, as amended and restated effective December 2, 2016, and all subsequent amendments thereto ("Agreement");

WHEREAS Conformis and Executive wish to amend the Agreement as stated herein; and

WHEREAS Conformis and Executive wish to confirm and ratify the Agreement, as amended.

NOW, THEREFORE, for and in consideration of the mutual covenants and promises herein contained, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. **Definitions.** Each capitalized term used but not defined in this Amendment shall have the meaning given to it in the Agreement, subject to any amendment of such term in this Amendment.

2. **Amended Provisions.** Conformis and Executive agree that, as of the Amendment Effective Date:

   a. Section 9 of the Agreement is hereby deleted in its entirety and amended as follows:

   "In connection with your employment with the Company, you will be expected to continue your regular presence at the Company's offices, and to maintain your secondary residence, in Massachusetts. In order to assist you with the costs associated with performing your role at the Company's Massachusetts offices, the Company shall provide you during your employment with a cost-of-living allowance ("COLA") in the gross amount of $44,642.86 payable quarterly, less required tax withholding. In addition, within ten (10) days of the Amendment Effective Date, the Company shall provide you with a one-time catch-up COLA payment in the gross amount of $5,952.71, less required tax withholding.";

   b. Section 13.B of the Agreement is hereby deleted in its entirety and amended as follows:

   "If a Qualifying Termination occurs (x) prior to three (3) months before or (y) more than twenty-four (24) months following a Change in Control Transaction, and the Qualifying Termination occurs on or after the two (2)-year anniversary of the Effective Date: (i) the Company will provide you with severance pay in the form of continuation of your base salary for a total of eighteen (18) months, such amount to be paid in accordance with the Company's then-current payroll practices, except as otherwise specified in this letter agreement, beginning on the Company's first regular payroll date that occurs after the Payment Date; (ii) the Company will pay to you (a) the bonus accrued by the Company for you for the calendar year that is prior to the year in which the Qualifying Termination occurs, provided the Company has not already paid you a Target Bonus (or other annual bonus) for the prior year, and (b) a bonus of seventy-five percent (75%) of your base salary for the calendar year in which the Qualifying Termination occurs; (iii) you will be eligible for the same COBRA premium assistance as set forth in Section 13.A above, subject to the same terms, conditions, and limitations as described therein; and (iv) the vesting of your then-outstanding unvested equity grants, if any, shall be accelerated in a number of shares that would have become vested had you continued as an employee of the Company for eighteen (18) months following a Qualifying Termination."; and

   c. Section 13.C of the Agreement is hereby deleted in its entirety and amended as follows:

   "If a Qualifying Termination occurs within three (3) months prior or twenty-four (24) months following a Change in Control Transaction, and regardless of whether the Qualifying Termination occurs prior to, on, or after the two (2)-year anniversary of the Effective Date: (i) the Company will provide you with severance pay in the form of continuation of your base salary for a total of twenty-four (24) months, such amount to be paid in accordance with the Company's then-current payroll practices, except as otherwise specified in this letter agreement, beginning on the Company's first regular payroll date that occurs after the Payment Date; (ii) the Company will pay to you the greater of (a) the bonus accrued by the Company for you for the calendar year that is prior to the year in which the Qualifying Termination occurs, provided the Company has not already paid you a Target Bonus (or other annual bonus) for the prior year, and (b) a bonus of seventy-five percent (75%) of your base salary for the calendar year in which the Qualifying Termination occurs and (b) an amount equal to 1.5 times the Target Bonus, to be paid in one lump sum on the Company's first regular payroll date that occurs after the Payment Date; (iii) you will be eligible for the same COBRA premium assistance as set forth in Section 13.A above, subject to the same terms, conditions, and limitations as described therein; and (iv) the vesting of one hundred percent (100%) of your then-outstanding unvested equity grants shall be accelerated, such that all unvested equity grants vest and become fully exercisable or non-forfeitable as of the date your employment terminates."

   All other terms and conditions of the Agreement remain in full force and effect.

3. **Counterparts.** This Amendment may be executed in one or more counterparts, all of which will be considered one and the same document, and will become effective when one or more counterparts have been signed by each of the parties and delivered to the other party. This Amendment may be executed and delivered by facsimile or e-mail transmission with the same effect as if a manually signed original was personally delivered.

4. **Ratification; Entire Agreement.** This Amendment shall not affect any of the terms or provisions of the Agreement other than those specified in this Amendment, and is only intended to amend, alter, or modify the Agreement as expressly stated herein. Except as amended hereby, the Agreement remains in effect, enforceable against each of the parties, and is hereby acknowledged and ratified by each of the parties. This Amendment shall be governed by and subject to the same terms, conditions, provisions, and rules of law or construction that apply according to the Agreement.

IN WITNESS WHEREOF, the parties execute this Amendment as of the Amendment Effective Date.

CONFORMIS	EXECUTIVE
By: /s/ Kenneth P. Fallon III	/s/ Mark A. Augusti
Kenneth P. Fallon III	Mark A. Augusti
Chairman of the Board	

December 19, 2019

Frederick Driscoll
2 Longbranch Ave
Rockport, MA 01966

Re: Extension of Service Period

Dear Fred:

Thank you for your continuing service to Conformis. We appreciate you being part of the team and your willingness to continue serving as Conformis' Interim Chief Financial Officer.

Sections 1 and 4 of your offer letter, dated October 14, 2019, describe the temporary nature of your employment and that your assignment is scheduled to last no later than December 31, 2019, *unless extended by Conformis in writing*. Consistent with your discussions with Mark Augusti, the purpose of this letter is to provide written notice that your temporary assignment has been extended and is now scheduled to last no later than March 31, 2020.

Please let me know if you have any questions.

Sincerely,

/s/ Allison Baker
Allison Baker
Director, Human Resources
Conformis, Inc.

FIRST AMENDMENT TO EMPLOYMENT AGREEMENT

This First Amendment to Employment Agreement ("Amendment"), entered into as of December 23, 2019 ("Amendment Effective Date"), is by and between Conformis, Inc. ("Conformis") and J. Brent Alldredge ("Executive").

WHEREAS Conformis and Executive are parties to that certain Employment Agreement dated July 29, 2019, and all subsequent amendments thereto ("Agreement");

WHEREAS Conformis and Executive wish to amend the Agreement as stated herein; and

WHEREAS Conformis and Executive wish to confirm and ratify the Agreement, as amended.

NOW, THEREFORE, for and in consideration of the mutual covenants and promises herein contained, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. **Definitions.** Each capitalized term used but not defined in this Amendment shall have the meaning given to it in the Agreement, subject to any amendment of such term in this Amendment.

2. **Amended Provisions.** Conformis and Executive agree that, as of the Amendment Effective Date:

   a. Section 2.1(h) of the Agreement is hereby deleted in its entirety and amended as follows:

      "'***Severance Period***' means the period following the date of a Qualifying Termination, Death Termination, or Disability Termination, as the case may be, that is equal to: (i) eighteen (18) months, in the event of a Qualifying Termination that occurs during a Change of Control Period; and (ii) twelve (12) months, in all other cases.";

   All other terms and conditions of the Agreement remain in full force and effect.

3. **Counterparts.** This Amendment may be executed in one or more counterparts, all of which will be considered one and the same document, and will become effective when one or more counterparts have been signed by each of the parties and delivered to the other party. This Amendment may be executed and delivered by facsimile or e-mail transmission with the same effect as if a manually signed original was personally delivered.

4. **Ratification; Entire Agreement.** This Amendment shall not affect any of the terms or provisions of the Agreement other than those specified in this Amendment, and is only intended to amend, alter, or modify the Agreement as expressly stated herein. Except as amended hereby, the Agreement remains in effect, enforceable against each of the parties, and is hereby acknowledged and ratified by each of the parties. This Amendment shall be

governed by and subject to the same terms, conditions, provisions, and rules of law or construction that apply according to the Agreement.

IN WITNESS WHEREOF, the parties execute this Amendment as of the Amendment Effective Date.

CONFORMIS	EXECUTIVE
By: /s/ Mark A. Augusti	/s/ J. Brent Alldredge
Mark A. Augusti President and Chief Executive Officer	J. Brent Alldredge

CONFORMIS, INC.

RESTRICTED STOCK AGREEMENT

Conformis, Inc. (the "Company") has selected you to receive the following restricted stock award, which is subject to the provisions of the Company's 2015 Stock Incentive Plan (the "Plan") and the terms and conditions contained in this Restricted Stock Agreement.

Name of Recipient: _____

Number of shares of restricted common stock awarded: _____

Grant Date: _____

Vesting Schedule: _____

All vesting is dependent on the Recipient's continued service to the Company as an independent sales representative.

Please confirm your acceptance of this restricted stock award and of the terms and conditions of this Agreement by signing a copy of this Agreement where indicated below.

CONFORMIS, INC.

By:_____
Name of Officer
Title:

Accepted and Agreed:

_____
[insert name of recipient]

CONFORMIS, INC.

RESTRICTED STOCK AGREEMENT

The terms and conditions of the award of shares of restricted common stock of the Company (the "Restricted Shares") made to the Recipient, as set forth on the cover page of this Agreement, are as follows:

1. Issuance of Restricted Shares.

(a) The Restricted Shares are issued to the Recipient, effective as of the Grant Date (as set forth on the cover page of this Agreement), in consideration of services rendered and to be rendered by the Recipient to the Company as an independent sales representative (the "Independent Sales Representative").

(b) The Restricted Shares will be issued by the Company in book entry form, in the name of the Recipient. The Recipient agrees that the Restricted Shares shall be subject to the forfeiture provisions set forth in Section 3 of this Agreement and the restrictions on transfer set forth in Section 4 of this Agreement.

2. Vesting. Unless otherwise provided in this Agreement or the Plan, the Restricted Shares shall vest in accordance with the vesting schedule set forth on the cover page of this Agreement. Any fractional number of Restricted Shares resulting from the application of such vesting schedule shall be rounded down to the nearest whole number of Restricted Shares.

3. Forfeiture of Unvested Restricted Shares Upon Cessation of Service.

In the event that the Recipient ceases to be an Independent Sales Representative to the Company, for any reason or no reason, with or without cause, all of the Restricted Shares that are unvested as of the time of such cessation shall be forfeited immediately and automatically to the Company, without the payment of any consideration to the Recipient, effective as of such cessation. The Recipient hereby authorizes the Company to take any actions necessary or appropriate to cancel any certificate(s) representing forfeited Restricted Shares and transfer ownership of such forfeited Restricted Shares to the Company; and if the Company or its transfer agent requires an executed stock power or similar confirmatory instrument in connection with such cancellation and transfer, the Recipient shall promptly execute and deliver the same to the Company. The Recipient shall have no further rights with respect to any Restricted Shares that are so forfeited.

4. Restrictions on Transfer.

The Recipient shall not sell, assign, transfer, pledge, hypothecate or otherwise dispose of, by operation of law or otherwise (collectively "transfer") any Restricted Shares, or any interest therein, until such Restricted Shares have vested, except that the Recipient may transfer such Restricted Shares: (a) to or for the benefit of any spouse, children, parents, uncles, aunts, siblings, grandchildren and any other relatives approved by the Compensation Committee (collectively, "Approved Relatives") or to a trust established solely for the benefit of the Recipient and/or Approved Relatives, provided that such Restricted Shares shall remain subject to this Agreement (including without limitation the forfeiture provisions set forth in Section 3 and the restrictions on transfer set forth in this Section 4) and such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Agreement; or (b) as part of the sale of all or substantially all of the shares of capital stock of the Company (including pursuant to a merger or consolidation). The Company shall not be required (i) to transfer on its books any of the Restricted Shares which have been transferred in violation of any of the provisions of this Agreement or (ii) to treat as owner of such Restricted Shares or to pay dividends to any transferee to whom such Restricted Shares have been transferred in violation of any of the provisions of this Agreement.

5. Restrictive Legends.

The book entry account reflecting the issuance of the Restricted Shares in the name of the Recipient shall bear a legend or other notation upon substantially the following terms:

"These shares of stock are subject to forfeiture provisions and restrictions on transfer set forth in a certain Restricted Stock Agreement between the corporation and the registered owner of these shares (or his or her predecessor in interest), and such Agreement is available for inspection without charge at the office of the Secretary of the corporation."

6. Rights as a Shareholder.

Except as otherwise provided in this Agreement, for so long as the Recipient is the registered owner of the Restricted Shares, the Recipient shall have all rights as a shareholder with respect to the Restricted Shares, whether vested or unvested, including, without limitation, rights to vote the Restricted Shares and act in respect of the Restricted Shares at any meeting of shareholders; provided that, as provided in the Plan, the payment of dividends on unvested Restricted Shares shall be deferred until the vesting of such shares.

7. Provisions of the Plan.

This Agreement is subject to the provisions of the Plan, a copy of which is furnished to the Recipient with this Agreement.

8. Tax Matters.

The Recipient acknowledges that he or she is responsible for obtaining the advice of the Recipient's own tax advisors with respect to the acquisition of the Restricted Shares, including with respect to the availability of making an election under Section 83(b) of the Internal Revenue Code of 1986, as amended, and the Recipient is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences relating to the Restricted Shares. The Recipient understands that the Recipient (and not the Company) shall be responsible for the Recipient's tax liability that may arise in connection with the acquisition, vesting and/or disposition of the Restricted Shares. The Recipient acknowledges and agrees that the Company shall have the right to deduct from payments of any kind otherwise due to the Recipient any federal, state, local or other taxes of any kind required by law to be withheld with respect to the grant or vesting of the Restricted Shares.

9. Miscellaneous.

(a) No Right to Continued Relationship. The Recipient acknowledges and agrees that, notwithstanding the fact that the vesting of the Restricted Shares is contingent upon his or her continued service to the Company as an Independent Sales Representative, this Agreement does not constitute an express or implied promise of continued service or confer upon the Recipient any rights with respect to continued service or any other relationship with the Company.

(b) Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflicts of laws provisions.

(c) Recipient's Acknowledgments. The Recipient acknowledges that he or she has read this Agreement, has received and read the Plan, and understands the terms and conditions of this Agreement and the Plan.

CONFORMIS, INC.
RESTRICTED STOCK UNIT AGREEMENT

Inducement Grant

Conformis, Inc. (the "Company") hereby grants the following restricted stock units. The terms and conditions attached hereto are also a part hereof.

Notice of Grant

Name of recipient (the "Participant"):	
Grant Date:	
Number of Restricted Stock Units ("RSUs") granted:	
Vesting Start Date:	

Vesting Schedule:

[__]% of the RSUs	
[__]% of the RSUs	
[__]% of the RSUs	
[__]% of the RSUs	
Except as provided herein, all vesting is dependent on the Participant continuing to perform services for the Company, as provided herein.	

This grant of RSUs satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

Participant

_____
[Participant Name]

_____
Street Address

_____
City/State/Zip Code

Conformis, Inc.

By:_____
Name of Officer:
Title:

Conformis, Inc.

Restricted Stock Unit Agreement
Incorporated Terms and Conditions

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Award of Restricted Stock Units.

In consideration of services to be rendered to the Company, by the Participant, the Company has granted to the Participant, subject to the terms and conditions set forth in this Restricted Stock Unit Agreement (this "Agreement"), an award with respect to the number of restricted shares units (the "RSUs") set forth in the Notice of Grant that forms part of this Agreement (the "Notice of Grant"). Each RSU represents the right to receive one share of common stock, $0.00001 par value per share, of the Company (the "Common Stock") upon vesting of the RSU, subject to the terms and conditions set forth herein.

The RSUs evidenced by this Agreement were granted to the Participant pursuant to the inducement grant exception under Nasdaq Stock Market Rule 5635(c)(4), and not pursuant to the Company's 2015 Stock Incentive Plan or any other equity incentive plan of the Company, as an inducement that is material to the Participant entering into employment with the Company.

2. Vesting Schedule.

The RSUs shall vest in accordance with the vesting schedule set forth on the Notice of Grant. Notwithstanding anything to the contrary in this Agreement, this award of RSUs shall be subject to the accelerated vesting provisions set forth in Section __ of that certain employment agreement by and between the Company and the Participant dated as of _____ __, 20__ (the "Employment Agreement")

Upon the vesting of the RSUs, the Company will deliver to the Participant, for each RSU that becomes vested, one share of Common Stock, subject to the payment of any taxes pursuant to Section 7. The Common Stock will be delivered to the Participant as soon as practicable following each vesting date, but in any event within 30 days of such date.

3. Forfeiture of Unvested RSUs Upon Cessation of Service.

In the event that the Participant ceases to perform services to the Company for any reason or no reason, with or without cause, all of the RSUs that are unvested as of the time of such cessation shall be forfeited immediately and automatically to the Company, without the payment of any consideration to the Participant, effective as of such cessation. The Participant shall have no further rights with respect to the unvested RSUs or any Common Stock that may have been issuable with respect thereto. If the Participant provides services to a subsidiary of the Company, any references in this Agreement to provision of services to the Company shall instead be deemed to refer to service with such subsidiary.

4. Transfer Restrictions; Clawback.

(a) The Participant shall not sell, assign, transfer, pledge, hypothecate or otherwise dispose of, by operation of law or otherwise (collectively "transfer") any RSUs, or any interest therein; provided, however, that the Board may permit for the gratuitous transfer of this award of RSUs by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act for the registration of the sale of the Common Stock subject to this award of RSUs to such proposed transferee; provided further, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of this award of RSUs. Reference to the Participant in this Agreement, to the extent relevant in context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 4 shall be deemed to restrict a transfer to the Company.

(b) In accepting these RSUs, the Participant agrees to be bound by any clawback policy that the Company has in place or may adopt in future.

5. Rights as a Stockholder.

The Participant shall have no rights as a stockholder of the Company with respect to any shares of Common Stock that may be issuable with respect to the RSUs until the issuance of the shares of Common Stock to the Participant following the vesting of the RSUs.

6. Tax Matters.

(a) Acknowledgments; No Section 83(b) Election. The Participant acknowledges that he or she is responsible for obtaining the advice of the Participant's own tax advisors with respect to the award of RSUs and the Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences relating to the RSUs. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's tax liability that may arise in connection with the acquisition, vesting and/or disposition of the RSUs. The Participant acknowledges that no election under Section 83(b) of the Internal Revenue Code, as amended, is available with respect to RSUs.

(b) Withholding. The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state, local or other taxes of any kind required by law to be withheld with respect to the vesting of the RSUs. At such time as the Participant is not aware of any material nonpublic information about the Company or the Common Stock, the Participant shall execute the instructions set forth in Exhibit A attached hereto (the "Automatic Sale Instructions") as the means of satisfying such tax obligation. If the Participant does not execute the Automatic Sale Instructions prior to an

applicable vesting date, then the Participant agrees that if under applicable law the Participant will owe taxes at such vesting date on the portion of the Award then vested the Company shall be entitled to immediate payment from the Participant of the amount of any tax required to be withheld by the Company. The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

7. Adjustments for Changes in Common Stock and Certain Other Events.

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, the number and class of securities subject to the RSUs shall be equitably adjusted by the Company in the manner determined by the Board.

(b) Reorganization Events. A "Reorganization Event" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (b) any transfer or disposition of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company. In connection with a Reorganization Event, the Board may take any one or more of the following actions with respect to the RSUs (or any portion thereof) on such terms as the Board determines: (i) provide that the RSUs shall be assumed, or substantially equivalent RSUs shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to the Participant, provide that the unvested portion of the RSUs will terminate immediately prior to the consummation of such Reorganization Event, (iii) provide that restrictions applicable to the RSUs shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "Acquisition Price"), make or provide for a cash payment to the Participant with respect to the RSUs equal to (A) the number of shares of Common Stock subject to the vested portion of the RSUs (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) any applicable tax withholdings, in exchange for the termination of the RSUs, (v) provide that, in connection with a liquidation or dissolution of the Company, the RSUs shall convert into the right to receive liquidation proceeds (if applicable, net of any applicable tax withholdings) and (vi) any combination of the foregoing.

For purposes of clause (i) above, the RSUs shall be considered assumed if, following consummation of the Reorganization Event, the RSUs confer the right to recieve, for each RSU immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock);

provided, however, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received to consist solely of such number of shares of common stock of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determined to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

8. Miscellaneous.

(a) No Right To Employment or Other Status. The award of these RSUs shall not be construed as giving the Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with the Participant free from any liability or claim hereunder, except as otherwise expressly provided herein or provided for in the Employment Agreement.

(b) Amendment. The Board may, from time to time, amend, modify or terminate this Agreement. Notwithstanding the foregoing, the Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant, or (ii) the change is permitted under Section 7 hereof or by the Employment Agreement.

(c) Acceleration. The Board may at any time provide that this award of RSUs shall become immediately vested in whole or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

(d) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to this Agreement until (i) all conditions of this Agreement have been met to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(e) Administration by Board. The Board will administer this Agreement and may construe and interpret the terms hereof. The Board may correct any defect, supply any omission or reconcile any inconsistency in this award of RSUs in the manner and to the extent it shall deem expedient to carry this Agreement into effect and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on the Participant. No individual acting as a director, officer, employee or agent of the Company will be liable to the Participant or any other person for any claim, loss, liability, or expense incurred in connection with this award of RSUs, nor will such individual be personally liable with respect to this award of RSUs because of any contract or

other instrument he or she executes in his or her capacity as a director, officer, employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, employee or agent of the Company to whom any duty or power relating to the administration or interpretation of this award of RSUs has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the award of RSUs unless arising out of such person's own fraud or bad faith.

(f) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers hereunder to one or more committees or subcommittees of the Board (a "Committee"). All references herein to the "Board" shall mean the Board or a Committee to the extent that the Board's powers or authority hereunder have been delegated to such Committee.

(g) Entire Agreement. This Agreement, together with the Employment Agreement, constitutes the entire agreement between the parties, and supersedes all prior agreements and understandings, relating to the subject matter hereof.

(h) Section 409A. The RSUs awarded pursuant to this Agreement are intended to be exempt from or comply with the requirements of Section 409A of the Internal Revenue Code and the Treasury Regulations issued thereunder ("Section 409A"). The delivery of shares of Common Stock on the vesting of the RSUs may not be accelerated or deferred unless permitted or required by Section 409A.

(i) Participant's Acknowledgements. The Participant acknowledges that he or she: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation and execution of this Agreement by legal counsel of the Participant's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; and (iv) is fully aware of the legal and binding effect of this Agreement.

(j) Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than the State of Delaware.

Exhibit A
Automatic Sale Instructions

The undersigned hereby consents and agrees that any taxes due on a vesting date as a result of the vesting of RSUs on such date shall be paid through an automatic sale of shares as follows:

(a) Upon any vesting of RSUs pursuant to Section 2 hereof, the

(b) Company shall arrange for the sale of such number of shares of Common Stock issuable with respect to the RSUs that vest pursuant to Sections 2 or 3 as is sufficient to generate net proceeds sufficient to satisfy the Company's minimum statutory withholding obligations with respect to the income recognized by the Participant upon the vesting of the RSUs (based on minimum statutory withholding rates for all tax purposes, including payroll and social security taxes, that are applicable to such income), and the Company shall retain such net proceeds in satisfaction of such tax withholding obligations.

(c) The Participant hereby appoints the [TITLE] and/or the [TITLE] of the Company his attorney in fact to sell the Participant's Common Stock in accordance with this Schedule A. The Participant agrees to execute and deliver such documents, instruments and certificates as may reasonably be required in connection with the sale of the Shares pursuant to this Exhibit A.

(d) The Participant represents to the Company that, as of the date hereof, he or she is not aware of any material nonpublic information about the Company or the Common Stock. The Participant and the Company have structured this Agreement, including this Schedule A, to constitute a "binding contract" relating to the sale of Common Stock, consistent with the affirmative defense to liability under Section 10(b) of the Securities Exchange Act of 1934 under Rule 10b5-1(c) promulgated under such Act.

The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

_____

Participant Name: _____

Date: _____

CONFORMIS, INC.
NONSTATUTORY STOCK OPTION AGREEMENT

Inducement Grant

Conformis, Inc. (the "Company") hereby grants the following stock option. The terms and conditions attached hereto are also a part hereof.

Notice of Grant

Name of optionee (the "Participant"):	
Grant Date:	
Number of shares of the Company's Common Stock subject to this option ("Shares"):	
Option exercise price per Share:	$
Vesting Start Date:	
Final Exercise Date:	

Vesting Schedule:

Vesting Date:	Number of Options that Vest:
First Anniversary of Vesting Start Date:	[__]% of the Shares
Each monthly anniversary of the First Anniversary of the Vesting Start Date:	[__] of the Shares
Except as provided herein, all vesting is dependent on the Participant remaining an Eligible Participant, as provided herein.	

This option satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

Conformis, Inc.

[Participant Name]

By:_____
Name of Officer:
Title:

Street Address

City/State/Zip Code

Conformis, Inc.

Nonstatutory Stock Option Agreement
Incorporated Terms and Conditions

1. Grant of Option.

This agreement evidences the grant by the Company, on the grant date (the "Grant Date") set forth in the Notice of Grant that forms part of this agreement (the "Notice of Grant") to the Participant of an option to purchase, in whole or in part, on the terms provided herein, the number of Shares set forth in the Notice of Grant of common stock, $0.00001 par value per share, of the Company ("Common Stock") at the exercise price per Share set forth in the Notice of Grant. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the Final Exercise Date set forth in the Notice of Grant (the "Final Exercise Date").

The option evidenced by this agreement was granted to the Participant pursuant to the inducement grant exception under Nasdaq Stock Market Rule 5635(c)(4), and not pursuant to the Company's 2015 Stock Incentive Plan (the "Plan") or any other equity incentive plan of the Company, as an inducement that is material to the Participant entering into employment with the Company.

It is intended that the option evidenced by this agreement shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

This option will become exercisable ("vest") in accordance with the vesting schedule set forth on the Notice of Grant. Notwithstanding anything to the contrary in this agreement, this option shall be subject to the accelerated vesting provisions set forth in Section __ of that certain employment agreement by and between the Company and the Participant dated as of _____ __, 20__ (the "Employment Agreement")

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing, in the form of the Stock Option Exercise Notice attached as Annex A, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, or in such other

form (which may be electronic) as is approved by the Company, together with payment in full as follows:

(1) in cash or by check, payable to the order of the Company;

(2) except as may otherwise be approved by the Board of Directors of the Company (the "Board"), in its sole discretion, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) to the extent approved by the Board, in its sole discretion, by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their fair market value per share of Common Stock as determined by (or in a manner approved by) the Board ("Fair Market Value"), provided (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board in its discretion and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent approved by the Board in its sole discretion, by delivery of a notice of "net exercise" to the Company, as a result of which the Participant would receive (i) the number of shares underlying the portion of this option being exercised, less (ii) such number of shares as is equal to (A) the aggregate exercise price for the portion of this option being exercised divided by (B) the Fair Market Value on the date of exercise;

(5) to the extent permitted by applicable law and approved by the Board, in its sole discretion, by payment of such other lawful consideration as the Board may determine; or

(6) by any combination of the above permitted forms of payment.

The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he exercises this option, is, and has been at all times since the Grant Date, an employee, director or officer of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event

after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's employment or other relationship with the Company is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination of employment or other relationship. "Cause" shall have the meaning set forth in any employment or other agreement between the Participant and the Company or, in the absence of such an agreement, shall mean, in the good faith determination of the Company, the Participant has: (i) committed gross negligence or willful malfeasance in the performance of the Participant's work or duties; (ii) committed a breach of fiduciary duty or a breach of any non-competition, non-solicitation or confidentiality obligations to the Company; (iii) failed to follow the proper directions of the Participant's direct or indirect supervisor after written notice of such failure; (iv) been convicted of, or pleaded "guilty" or "no contest" to, any misdemeanor relating to the affairs of the Company or any felony; (v) disregarded the material rules or material policies of the Company which has not been cured within 15 days after notice thereof from the Company; or (vi) engaged in intentional acts that have generated material adverse publicity toward or about the Company.

4. Withholding.

No Shares will be issued pursuant to the exercise of this option nor will the Company otherwise recognize ownership of Common Stock under this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option. The Company may decide to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise of this option or at the same time as payment of the exercise price, unless the Company

determines otherwise. If approved by the Board in its sole discretion, the Participant may satisfy such tax obligations in whole or in part by delivery (either by actual delivery or attestation) of shares of Common Stock, including shares of Common Stock underlying this option, valued at their Fair Market Value; provided, however, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income). Shares used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

5. Transfer Restrictions; Clawback.

a. This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant; provided, however, that the Board may permit for the gratuitous transfer of this option by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act for the registration of the sale of the Common Stock subject to this option to such proposed transferee; provided further, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of this option. For the avoidance of doubt, nothing contained in this Section 5 shall be deemed to restrict a transfer to the Company.

b. In accepting this option, the Participant agrees to be bound by any clawback policy that the Company has in place or may adopt in future.

6. Adjustments for Changes in Common Stock and Certain Other Events.

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, the number and class of securities and exercise price per share of this option shall be equitably adjusted by the Company in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to this option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then the Participant, if he exercises this option between the record date and the distribution date for such stock dividend, shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon exercise of this option, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(b) Reorganization Events.

(1) A "Reorganization Event" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (b) any transfer or disposition of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company.

(2) In connection with a Reorganization Event, the Board may take any one or more of the following actions with respect to this option (or any portion thereof) on such terms as the Board determines: (i) provide that this option shall be assumed, or substantially equivalent option shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to the Participant, provide that the unvested and/or unexercised portion of this option will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that this option shall become exercisable, realizable, or deliverable, or restrictions applicable to this option shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "Acquisition Price"), make or provide for a cash payment to the Participant with respect to this option equal to (A) the number of shares of Common Stock subject to the vested portion of this option (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise price of this option and any applicable tax withholdings, in exchange for the termination of this option, (v) provide that, in connection with a liquidation or dissolution of the Company, this option shall convert into the right to receive liquidation proceeds (net of the exercise price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing.

(3) For purposes of clause 6(b)(2)(i) above, this option shall be considered assumed if, following consummation of the Reorganization Event, this option confers the right to purchase, for each share of Common Stock subject to this option immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); provided, however, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise of this option to consist solely of such number of shares of common stock of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determined to be equivalent in value (as of the date of such determination or another date specified by the Board)

to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

7. Miscellaneous.

(a) No Right To Employment or Other Status. The grant of this option shall not be construed as giving the Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with the Participant free from any liability or claim hereunder, except as otherwise expressly provided herein or provided for in the Employment Agreement.

(b) No Rights As Stockholder. Subject to the provisions of this option, the Participant shall not have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to this option until becoming the record holder of such shares.

(c) Amendment. The Board may amend, modify or terminate this agreement, including but not limited to, substituting another option of the same or a different type and changing the date of exercise or realization. Notwithstanding the foregoing, the Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant, or (ii) the change is permitted under Section 6 hereof or by the Employment Agreement.

(d) Acceleration. The Board may at any time provide that this option shall become immediately exercisable in whole or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

(e) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to this agreement until (i) all conditions of this agreement have been met to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(f) Administration by Board. The Board will administer this agreement and may construe and interpret the terms hereof. The Board may correct any defect, supply any omission or reconcile any inconsistency in this option in the manner and to the extent it shall deem expedient to carry this agreement into effect and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on the Participant. No individual acting as a director, officer, employee or agent of the Company will be liable to the Participant or any other person for any claim, loss, liability, or expense incurred in connection with this option, nor will such individual be personally liable with respect to this option because of any contract or other instrument he or she executes in his or her capacity as a director, officer, employee or agent of the Company. The

Company will indemnify and hold harmless each director, officer, employee or agent of the Company to whom any duty or power relating to the administration or interpretation of this option has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the option unless arising out of such person's own fraud or bad faith.

(g) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers hereunder to one or more committees or subcommittees of the Board (a "Committee"). All references herein to the "Board" shall mean the Board or a Committee to the extent that the Board's powers or authority hereunder have been delegated to such Committee.

(h) Entire Agreement. This Agreement, together with the Employment Agreement, constitutes the entire agreement between the parties, and supersedes all prior agreements and understandings, relating to the subject matter hereof.

(i) Governing Law. This agreement shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than the State of Delaware.

ANNEX A

Conformis, Inc.

Stock Option Exercise Notice

Conformis, Inc.
600 Technology Park Drive
Billerica, MA 01821

Dear Sir or Madam:

I, _____(the "Participant"), hereby irrevocably exercise the right to purchase ____ shares of the Common Stock, $0.00001 par value per share (the "Shares"), of Conformis, Inc. (the "Company") at $___ per share pursuant to a stock option agreement with the Company dated _____(the "Option Agreement"). Enclosed herewith is a payment of $____, the aggregate purchase price for the Shares. The certificate for the Shares should be registered in my name as it appears below or, if so indicated below, jointly in my name and the name of the person designated below, with right of survivorship.

Dated: _____

Signature
Print Name:

Address:

_____
_____

Name and address of persons in whose name the Shares are to be jointly registered (if applicable):

_____

FIFTH AMENDMENT TO AMENDED
AND RESTATED EMPLOYMENT AGREEMENT

This Fifth Amendment to Amended and Restated Employment Agreement ("Amendment"), entered into as of February 5, 2020 ("Amendment Effective Date"), is by and between Conformis, Inc. ("Conformis") and Mark A. Augusti ("Executive").

WHEREAS Conformis and Executive are parties to that certain letter agreement of employment dated October 19, 2016, as amended and restated effective December 2, 2016, and all subsequent amendments thereto ("Agreement");

WHEREAS Conformis and Executive wish to amend the Agreement as stated herein; and

WHEREAS Conformis and Executive wish to confirm and ratify the Agreement, as amended.

NOW, THEREFORE, for and in consideration of the mutual covenants and promises herein contained, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. **Definitions.** Each capitalized term used but not defined in this Amendment shall have the meaning given to it in the Agreement, subject to any amendment of such term in this Amendment.

2. **Amended Provisions.** Conformis and Executive agree that, as of the Amendment Effective Date:

   a. Section 6 of the Agreement is hereby deleted in its entirety and amended as follows:

   "Beginning in 2017, following the end of each calendar year, you will be eligible for an annual target bonus of 75% of your annualized base salary (the 'Target Bonus'), based upon achievement of both corporate and your individual goals, as determined by the Board in its sole discretion. Beginning in 2020, such Target Bonus will increase from 75% to 85% (i.e., you will be eligible to receive a target bonus of 75% in 2020 based upon achievement of 2019 goals and a target bonus of 85% in 2021 based upon achievement of 2020 goals). The determination of whether a bonus will be granted, and the amount of any such bonus, will also be determined by the Board in its sole discretion. (For the avoidance of doubt, annual bonus eligibility may range above or below target, consistent with the structure of any applicable plan as applied to similarly situated Company executives.) Any annual bonus will be payable no later than March 15 of the year following the year to which it relates. Please note that you must be an active employee on the date any bonus is distributed (the 'Bonus Payment Date') in order to be eligible for and to earn a bonus, as annual bonuses also serve as retention incentives. For the avoidance of doubt, you will not be eligible to receive any annual bonus for 2016.";

   b. Section 13.B of the Agreement is hereby deleted in its entirety and amended as follows:

   "If a Qualifying Termination occurs (x) prior to three (3) months before or (y) more than twenty-four (24) months following a Change in Control Transaction, and the Qualifying Termination occurs on or after the two (2)-year anniversary of the Effective Date: (i) the Company will provide you with severance pay in the form of continuation of your base salary for a total of eighteen (18) months, such amount to be paid in accordance with the Company's then-current payroll practices, except as otherwise specified in this letter agreement, beginning on the Company's first regular payroll date that occurs after the Payment Date; (ii) the Company will pay to you (a) the bonus accrued by the Company for you for the calendar year that is prior to the year in which the Qualifying Termination occurs, provided the Company has not already paid you a Target Bonus (or other annual bonus) for the prior year, and (b) a bonus of eighty-five percent (85%) of your base salary for the calendar year in which the Qualifying Termination occurs; (iii) you will be eligible for the same COBRA premium assistance as set forth in Section 13.A above, subject to the same terms, conditions, and limitations as described therein; and (iv) the vesting of your then-outstanding unvested equity grants, if any, shall be accelerated in a number of shares that would have become vested had you continued as an employee of the Company for eighteen (18) months following a Qualifying Termination."; and

   c. Section 13.C of the Agreement is hereby deleted in its entirety and amended as follows:

   "If a Qualifying Termination occurs within three (3) months prior or twenty-four (24) months following a Change in Control Transaction, and regardless of whether the Qualifying Termination occurs prior to, on, or after the two (2)-year anniversary of the Effective Date: (i) the Company will provide you with severance pay in the form of continuation of your base salary for a total of twenty-four (24) months, such amount to be paid in accordance with the Company's then-current payroll practices, except as otherwise specified in this letter agreement, beginning on the Company's first regular payroll date that occurs after the Payment Date; (ii) the Company will pay to you the greater of (a) the bonus accrued by the Company for you for the calendar year that is prior to the year in which the Qualifying Termination occurs, provided the Company has not already paid you a Target Bonus (or other annual bonus) for the prior year, and (b) a bonus of eighty-five percent (85%) of your base salary for the calendar year in which the Qualifying Termination occurs and (b) an amount equal to 1.5 times the Target Bonus, to be paid in one lump sum on the Company's first regular payroll date that occurs after the Payment Date; (iii) you will be eligible for the same COBRA premium assistance as set forth in Section 13.A above, subject to the same terms, conditions, and limitations as described therein; and (iv) the vesting of one hundred percent (100%) of your then-outstanding unvested equity grants shall be accelerated, such that all unvested equity grants vest and become fully exercisable or non-forfeitable as of the date your employment terminates."

   All other terms and conditions of the Agreement remain in full force and effect.

3. **Counterparts.** This Amendment may be executed in one or more counterparts, all of which will be considered one and the same document, and will become effective when one or more counterparts have been signed by each of the parties and delivered to the other party. This Amendment may be executed and delivered by facsimile or e-mail transmission with the same effect as if a manually signed original was personally delivered.

4. **Ratification; Entire Agreement.** This Amendment shall not affect any of the terms or provisions of the Agreement other than those specified in this Amendment, and is only intended to amend, alter, or modify the Agreement as expressly stated herein. Except as amended hereby, the Agreement remains in effect, enforceable against each of the parties, and is hereby acknowledged and ratified by each of the parties. This Amendment shall be governed by and subject to the same terms, conditions, provisions, and rules of law or construction that apply according to the Agreement.

IN WITNESS WHEREOF, the parties execute this Amendment as of the Amendment Effective Date.

CONFORMIS	EXECUTIVE
By: /s/ Kenneth P. Fallon III Kenneth P. Fallon III Chairman of the Board	/s/ Mark A. Augusti Mark A. Augusti

CONFORMIS, INC.

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "***Agreement***") is made and entered into as of February 17, 2020 (the "***Effective Date***") by and between Conformis, Inc., a Delaware corporation (the "***Company***"), and Robert Howe, an individual residing at 10 Cricket Court, Stow, Massachusetts 01775 (the "***Executive***").

BACKGROUND

A. The Company desires to retain the services of the Executive as a member of the senior management of the Company from the Start Date (defined below). The Company also desires to provide employment security to the Executive, thereby inducing the Executive to continue employment with the Company and enhancing the Executive's ability to perform effectively.

B. The Executive desires to be employed by the Company on the terms and subject to the conditions set forth in this Agreement.

THE PARTIES AGREE AS FOLLOWS:

1. ***Title, Duties and Responsibilities***.

1.1 ***Title***. The Company will employ the Executive as Chief Financial Officer.

1.2 ***Duties***. The Executive will devote all of the Executive's business time, energy, and skill to the affairs of the Company; provided, however, that reasonable time for personal business as well as charitable and professional activities will be permitted, including, with the prior written approval of the Company, serving as a board member of non-competing companies and charitable organizations, so long as such activities do not materially interfere with the Executive's performance of services under this Agreement. The Executive will perform services at the head offices of the Company, which are currently located in Billerica, Massachusetts, unless otherwise agreed by the Company and the Executive in writing. However, the Executive will travel as may be reasonably necessary to fulfill the responsibilities of Executive's role.

1.3 ***Performance of Duties***. The Executive will discharge the duties described herein in a diligent and professional manner. The Executive will report to the Company's Chief Executive Officer and observe and comply at all times with the lawful directives of the Company's Board of Directors (and its designees, including, without limitation, the Company's Chief Executive Officer) (the "***Board***") regarding the Executive's performance of the Executive's duties and with the Company's business policies, rules and regulations as adopted from time to time by the Company. The Executive will carry out and perform any and all reasonable and

lawful orders, directions, and policies as may be stated by Company from time to time, either orally or in writing.

1.4 ***Start Date***. The Executive's first day of employment shall be February 17, 2020 (the "***Start Date***".)

2. ***Terms of Employment***.

2.1 ***Definitions***. For purposes of this Agreement, the following terms have the following meanings:

(a) "***Accrued Compensation***" means any accrued Base Salary, any commissions or similar payments earned by the Executive prior to the date of termination, any Bonus earned by the Executive and approved by the Board prior to the date of termination, any accrued PTO (defined below), and any amounts for reimbursement of any appropriate business expenses incurred by the Executive in connection with the performance of the Executive's duties hereunder, all to the extent unpaid on the date of termination. The Executive's entitlement to any other compensation or benefit under any plan of the Company shall be governed by and determined in accordance with the terms of such plans, except as otherwise specified in this Agreement.

(b) "***Base Salary***" has the meaning set forth in Section 3.1 hereof.

(c) "***Change of Control***" means the occurrence of any one of the following: (i) any "person", as such term is used in Section 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***") (other than the Company, a subsidiary, an affiliate, or a Company employee benefit plan, including any trustee of such plan acting as trustee) is or becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities; or (ii) a sale of assets involving 75% or more of the fair market value of the assets of the Company as determined in good faith by the Board; or (iii) any merger, reorganization or other transaction of the Company whether or not another entity is the survivor, pursuant to which holders of all the shares of capital stock of the Company outstanding prior to the transaction hold, as a group, less than fifty percent (50%) of the shares of capital stock of the Company outstanding after the transaction; provided, however, that neither (A) a merger effected exclusively for the purpose of changing the domicile of the Company in which the holders of all the shares of capital stock of the Company immediately prior to the merger hold the voting power of the surviving entity following the merger in the same relative amounts with substantially the same rights, preferences and

privileges, nor (B) a transaction the primary purpose of which is to raise capital for the Company, will constitute a Change of Control. Notwithstanding the foregoing, for any payments or benefits hereunder or pursuant to any other agreement between the Company and the Executive, in either case that are subject to Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***"), the Change of Control must constitute a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i).

(d) "***Change of Control Period***" means the period of time beginning three (3) months immediately preceding any Change of Control and ending twelve (12) months immediately following such Change of Control.

(e) "***Death Termination***" means termination of the Executive's employment because of the death of the Executive.

(f) "***Disability Termination***" means termination by the Company of the Executive's employment by reason of the Executive's incapacitation due to disability. The Executive will be deemed to be incapacitated due to disability if at the end of any month the Executive is unable to perform substantially all of the Executive's duties under this Agreement in the normal and regular manner due to illness, injury or mental or physical incapacity, and has been unable so to perform for either (i) three (3) consecutive full calendar months then ending, or (ii) ninety (90) or more of the normal working days during the twelve (12) consecutive full calendar months then ending. Nothing in this paragraph alters the Company's obligations under applicable law, which may, in certain circumstances, result in the suspension or alteration of the foregoing time periods.

(g) "***Qualifying Termination***" means a termination that: (i) is a Termination for Good Reason by the Executive and/or a Termination Other Than for Cause by the Company; and (ii) occurs at least ninety (90) days following the Effective Date.

(h) "***Severance Period***" means the period following the date of a Qualifying Termination, Death Termination, or Disability Termination, as the case may be, that is equal to: (i) eighteen (18) months, in the event of a Qualifying Termination that occurs during a Change of Control Period; and (ii) twelve (12) months, in all other cases.

(i) "***Termination for Cause***" means termination by the Company of the Executive's employment, pursuant to a reasonable good faith determination by the Company, by reason of (i) the Executive's dishonesty or fraud, gross negligence in the performance of the Executive's duties and responsibilities, deliberate violation of a Company policy, or refusal to comply in any material respect with the legal directives of the Board or Chief Executive Officer so long as such directives are not inconsistent with the Executive's position and duties as described herein; (ii) conduct by the Executive that materially discredits the Company, intentional engagement by the Executive in acts materially detrimental to the Company's operations or business, persistent or habitual negligence in the performance of the Executive's

duties and responsibilities, or the Executive's conviction of a felony involving moral turpitude; (iii) the Executive's incurable material breach of the terms of this Agreement, the Employee Confidential Information, Inventions and Non-Competition Agreement or any other material agreement between the Executive and the Company; or (iv) unauthorized use or disclosure by the Executive of any proprietary information or trade secrets of the Company or any other party to whom the Executive owes an obligation of nondisclosure as a result of the Executive's position with the Company.

(j) "***Termination for Good Reason***" means a Voluntary Termination by the Executive following the occurrence of any of the following events: (i) a material reduction or alteration in the Executive's job responsibilities or title without the consent of the Executive, provided that, following a Change of Control, neither a change in job title nor a reassignment to a new position will constitute a material reduction in job responsibilities, provided further that the new position is substantially similar in scope and substance to the position held prior to the Change of Control and the new job title reasonably reflects such scope and substance; (ii) relocation by the Company or a subsidiary, parent or affiliate, as appropriate, of the Executive's work site to a facility or location more than forty (40) miles from Billerica, Massachusetts, provided that the change in location does not decrease the Executive's commute, without the Executive's consent; (iii) a material reduction in Executive's then-current base salary without the Executive's consent, provided that an across-the-board reduction in the salary level of all other employees or consultants in positions similar to the Executive's by the same percentage amount as part of a general salary level reduction will not constitute such a salary reduction; or (iv) a material breach by the Company of this Agreement (each event a "Good Reason"); provided, however, that no such event or condition shall constitute Good Reason unless (x) the Executive gives the Company a written notice of Termination for Good Reason not more than thirty (30) days after the initial existence of the condition, (y) the grounds for termination (if susceptible to correction) are not corrected by the Company within sixty (60) days of its receipt of such notice and (z) the Executive's Voluntary Termination occurs within the earlier of (i) ninety (90) days following the Company's receipt of such notice or (ii) thirty (30) days following Executive's receipt from Company of a notice indicating that it does not intend to correct the grounds for termination and/or that the Company disputes that the grounds for terminations constitute a Qualifying Termination.

(k) "***Termination Other Than For Cause***" means termination of the Executive's employment for any reason other than as specified in Sections 2.1(e), (f), (i) or (l) hereof.

(l) "***Voluntary Termination***" means termination of the Executive's employment by the voluntary action of the Executive other than by reason of a Disability Termination or a Death Termination.

2.2 ***Employee at Will***. The Executive is an "at will" employee of the Company, and the Executive's employment may be terminated at any time upon a Termination for Cause or a Termination Other than for Cause by the giving of written notice thereof to the Executive, subject to the terms and conditions of this Agreement.

2.3 ***Termination for Cause***. Upon Termination for Cause, the Company will pay the Executive all Accrued Compensation, if any.

2.4 ***Terminations for Good Reason or Other than for Cause***. Upon a Qualifying Termination, the Company will pay the Executive all Accrued Compensation, if any, and for the duration of the Severance Period, the Company will: (1) continue to pay the Executive's Base Salary at the rate in effect at the time of such Qualifying Termination, payable on the Company's normal payroll schedule, beginning on the Company's first regular payroll date that occurs on or after the 30th day following the date of the Qualifying Termination, provided that the Release (as defined below) has been executed and any applicable revocation period has expired as of such date; and (2) provide Executive with continuation of the Executive's health insurance coverage in effect at the time of such Qualifying Termination under the Company's group health insurance plans (to the extent allowed under, and subject to the conditions of, the Consolidated Omnibus Budget Reconciliation Act (COBRA)), provided that the Release (as defined below) has been executed and any applicable revocation period has expired as of such date. The Executive's rights to any compensations or other benefits following a Qualifying Termination, other than Accrued Compensation, are subject to: (1) the execution by Executive of a separation and release agreement in a form to be provided by the Company (the "***Release***"), including a release of any and all claims against the Company (including, without limitation, its subsidiaries, other affiliates, directors, officers, employees, agents and representatives) related in any way to the Executive's employment with the Company, such Release to be executed following the Executive's separation from service with the Company; (2) the expiration of any revocation period provided pursuant to any applicable laws; and (3) Executive's continued compliance with the ongoing terms of Executive's Confidentiality, Inventions Assignment and Non-Competition Agreement.

2.5 ***Disability Termination***. The Company may effect a Disability Termination by giving written notice thereof to the Executive. Upon Disability Termination, the Company will pay the Executive all Accrued Compensation, if any.

2.6 ***Death Termination***. Upon a Death Termination, the Executive's employment will be deemed to have terminated as of the last day of the month during which his death occurs, and the Company will promptly pay to the Executive's estate Accrued Compensation, if any, and a lump sum amount equal to the Executive's Base Salary otherwise payable for the Severance Period at the rate in effect at the time of Death Termination.

2.7 ***Voluntary Termination***. The Executive may effect a Voluntary Termination by giving at least thirty (30) days' advance written notice to the Company. During such period, the

Executive will continue to receive regularly scheduled Base Salary payments and coverage under the Company's benefit plans in which the Executive is a participant (to the extent allowed under any applicable benefit plans), provided, however, that the Company shall have the right to accelerate the effective date of the Voluntary Termination to any earlier date during such period and pay to the Executive any regularly scheduled Base Salary payments for such period in a lump sum on the date of termination. Following the effective date of a Voluntary Termination, the Company will pay the Executive all Accrued Compensation, if any.

3. ***Compensation and Benefits***.

3.1 ***Base Salary***. As payment for the services to be rendered by the Executive as provided in Section 1 and subject to the provisions of Section 2 of this Agreement, the Company will pay the Executive a "Base Salary" at the rate of $340,000.00 per year, payable on the Company's normal payroll schedule. The Executive's "Base Salary" may be increased in accordance with the provisions hereof or as otherwise determined from time to time by the Board.

3.2 ***Additional Benefits***.

(a) ***Benefit Plans***. The Executive will be eligible to participate in such of the Company's benefit plans as are now generally available or later made generally available to senior officers of the Company, including, without limitation, medical, dental, life, and disability insurance plans.

(b) ***Expense Reimbursement***. The Company agrees to reimburse the Executive for all reasonable, ordinary and necessary travel and entertainment expenses incurred by the Executive in conjunction with the Executive's services to the Company consistent with the Company's standard reimbursement policies, subject to Section 6.11(c). The Company will pay travel costs incurred by the Executive in conjunction with the Executive's services to the Company consistent with the Company's standard travel policies.

(c) ***Paid Time Off***. The Executive will be entitled, without loss of compensation, to the amount of Paid Time Off ("***PTO***") per year generally available or later made generally available to senior officers of the Company, but in any event not less than five (5) weeks (200 hours) during each calendar year, prorated from the Start Date. Unused PTO may be accrued by the Executive pursuant to the Company's standard PTO policies.

(d) ***Incentive Compensation***. Commencing as of the Start Date, the Executive will be eligible annually to receive a discretionary year-end bonus of forty percent (40%) of the Executive's Base Salary, payable in the following calendar year in the form of cash, restricted stock, an option to purchase common stock of the Company, or other form determined by the Board (the "***Bonus***"). The Bonus will be awarded at the discretion of the Board and may be subject to terms (including, without limitation, incentive targets, goals and/or milestones) as set

by the Board and/or Chief Executive Officer, and the bonus will be pro-rated for the 2020 calendar year based on the percentage of the year the Executive is employed by the Company; provided, however, that the Company agrees to pay to the Executive, for the 2020 calendar year only, a minimum bonus of $100,000.00 in cash. Any Bonus in the form of an option to purchase Company's Common Stock will be granted at the then fair market value of such shares pursuant to the Company's standard form of notice of stock option grant under the Company's 2015 Stock Option/Stock Issuance Plan or any successor plan(s). The Executive acknowledges that the Company may pay Bonuses in the form of stock, stock options or other non-cash compensation in lieu of cash, and that entitlement to Bonuses and the form thereof (i.e., cash or otherwise) is in the sole discretion of the Board. The Executive must be employed by the Company on the date the Bonus is approved by the Board in order to be eligible to receive such Bonus. The Executive will also be eligible for annual equity grants, subject to the then-current program as it applies to similarly situated executive employees and to approval by the Board, in its sole discretion. For purposes of clarity, a grant of equity or other compensation expressly provided as a long-term incentive or for another expressly stated purpose, or that is not expressly provided as a Bonus to Executive, is not a Bonus for purposes of this Agreement.

(e) ***Signing Bonus***. The executive shall receive a cash signing bonus of $90,000.00, less applicable taxes and withholding, and paid with the first regularly scheduled payroll following the Start Date. In the event the Executive effects a Voluntary Termination of his employment with the Company or if the Company terminates the Executive's employment for Cause within twelve (12) months of the Start Date, then the Executive shall be required to repay the Company for the full amount of the signing bonus within thirty (30) days following the date of termination.

3.3 ***Options to Purchase Common Stock***.

(a) ***Option to Purchase Common Stock.*** The senior management of the Company will recommend that the Board grant the Executive an option to purchase 125,000 shares of the Company's common stock, $0.00001 par value per share (the "***Common Stock***") having an exercise price equal to the fair market value of the Company's Common Stock as of the grant date and that such stock option shall have a term of ten (10) years (the "***Option***").

(b) ***Vesting.*** The Option would vest with respect to twenty-five percent (25%) of the total number of shares purchasable upon exercise thereof one (1) year after the Start Date and ratably on a monthly basis thereafter over an additional three (3) years, and would cease to vest if the Executive's service as an employee of the Company is terminated for any reason, except as described in Sections 2.4-2.6 and 3.5.

(c) ***Form of Option.*** The Option would be granted pursuant to the inducement grant exception under Nasdaq Rule 5635(c)(4) and not pursuant to the Company's 2015 Stock Option Incentive Plan or any other equity incentive plan of the Company, as an inducement that is material to the Executive's entering into employment with the Company. The

Option would also be subject to such other terms and conditions as are set forth in the applicable Option award agreement.

3.4 ***Grant of Restricted Stock Units***.

(a) ***Restricted Stock Award.*** The senior management of the Company will recommend that the Board grant the Executive the right to receive 125,000 restricted stock units ("***RSUs***"), each RSU entitling the Executive to receive, upon vesting, one share of the Company's Common Stock (the "***RSU Award***").

(b) ***Vesting.*** The RSU Award would vest in equal annual installments on the first four (4) anniversaries of the Start Date, and will cease to vest if the Executive's service as an employee of the Company is terminated for any reason, except as described in Sections 2.4-2.5 and 3.5.

(c) ***Form of RSU Award.*** The RSU Award would be granted pursuant to the inducement grant exception under Nasdaq Rule 5635(c)(4) and not pursuant to the Company's 2015 Stock Option Incentive Plan or any other equity incentive plan of the Company, as an inducement that is material to the Executive entering into employment with the Company. The RSU Award would also be subject to such other terms and conditions as are set forth in the applicable RSU Award agreement.

3.5 ***Acceleration of Vesting upon a Change of Control***. Upon the occurrence of Qualifying Termination during any Change of Control Period, any outstanding equity awards held by the Executive will become, subject to the Release becoming effective and irrevocable, fully vested and exercisable or free from forfeiture or transfer restrictions as of the effective date of the Qualifying Termination (provided that if such Qualifying Termination precedes the Change of Control, such accelerated vesting shall be effective as of the effective date of the Change of Control).

4. ***Proprietary Information***. The Executive will as of the Effective Date execute and deliver to the Company the Employee Confidential Information, Inventions and Non-Competition Agreement attached as Exhibit A hereto.

5. ***Indemnification***. The Company will indemnify and hold harmless the Executive in respect of any liability, damage, amount paid in settlement, cost or expense (including reasonable attorneys' fees) incurred in connection with any threatened, pending or completed claim, action, suit, proceeding or investigation (whether civil, criminal or administrative) to which the Executive is or was a party, or threatened to be made a party, by reason of the Executive being or having been an officer, director, employee or consultant of the Company or serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, limited liability company, joint venture, trust or other enterprise to the full extent required by the

Company's Articles of Incorporation or Bylaws of the Company and not prohibited by applicable law. This Section 5 will survive the termination or expiration of this Agreement.

6. ***Miscellaneous***.

6.1 ***Waiver***. The waiver of the breach of any provision of this Agreement will not operate or be construed as a waiver of any subsequent breach of the same or other provision hereof.

6.2 ***Notices***. All notices and other communications under this Agreement must be in writing and must be given by personal or courier delivery, facsimile or first class mail, certified or registered with return receipt requested, and will be deemed to have been duly given upon receipt if personally delivered or delivered by courier, on the date of transmission if transmitted by facsimile, or three (3) business days after mailing if mailed, to the addresses of the Company and the Executive contained in the records of the Company at the time of such notice. Any party may change such party's address for notices by notice duly given pursuant to this Section 6.2.

6.3 ***Headings***. The section headings used in this Agreement are intended for convenience of reference and will not by themselves determine the construction or interpretation of any provision of this Agreement.

6.4 ***Governing Law***. This Agreement is governed by and, to the extent a dispute arises hereunder, will be construed in accordance with the laws of the Commonwealth of Massachusetts, excluding those laws that direct the application of the laws of another jurisdiction.

6.5 ***Arbitration***. Any controversy or claim arising out of, or relating to, the Executive's employment with the Company, this Agreement, or the breach of this Agreement (except any controversy or claim arising out of, or relating to, Exhibit A or the breach of Exhibit A) will be settled by arbitration by, and in accordance with the applicable National Rules for the Resolution of Employment Disputes, of the American Arbitration Association and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction; provided, however, that nothing in this Section requires the arbitration of disputes or claims for a temporary restraining order or preliminary injunction in cases in which such temporary equitable relief would be otherwise authorized by law. For clarification, but not limitation, the Executive agrees to arbitrate: (i) any claims of unlawful discrimination, harassment, or retaliation under federal, state, or local laws or regulations; (ii) any claim for unpaid or late payment of wages, reimbursement of expenses, or any violation of federal, state, or local wage and hour laws or regulations; (iii) any whistleblower claim or claim alleging unfair business practices under any federal, state or local law; and (iv) any claim arising out of any and all common law claims, including, but not limited to, actions in contract, express or implied (including any claim relating to the interpretation, existence, validity, scope or enforceability of this arbitration provision), estoppel, tort, emotional distress, invasion of privacy, or defamation. The Company shall pay

any filing fee and the fees and costs of the Arbitrator(s); provided, however, that if the Executive is the party initiating the arbitration, the Executive will pay an amount equivalent to the filing fee that the Executive would have paid to file a civil action or initiate a claim in the court of general jurisdiction in the state in which the Executive performed services for the Company. Each party shall pay for its own costs and attorneys' fees, if any; provided, however, that if either party prevails on a statutory claim which affords the prevailing party attorneys' fees and costs, the Arbitrator(s) may award reasonable attorneys' fees and/or costs to such prevailing party, applying the same standards a court would apply under the law applicable to the claim(s). Arbitration hearings will be held in Middlesex County, Massachusetts. Both parties expressly waive any right that any party either has or may have to a jury trial of any dispute subject to arbitration under this provision. Except as otherwise required under applicable law, (1) both parties agree that neither will assert class action or representative action claims against the other, whether in arbitration or otherwise, which actions are hereby waived; and (2) each party shall only submit their own, individual claims in arbitration and will not seek to represent the interests of any other person.

6.6 ***Survival of Obligations***. This Agreement will be binding upon and inure to the benefit of the executors, administrators, heirs, successors, and assigns of the parties; provided, however, that except as herein expressly provided, this Agreement will not be assignable either by the Company (except to an affiliate or successor of the Company) or by the Executive without the prior written consent of the other party.

6.7 ***Counterparts and Facsimile Signatures***. This Amendment may be executed in one or more counterparts, and by facsimile or scanned and electronically mailed or otherwise electronically transferred signatures, each of which shall be an original document, and all of which together will constitute one and the same instrument.

6.8 ***Withholding***. All sums payable to the Executive hereunder will be reduced by all federal, state, local, and other withholdings and similar taxes and payments required by applicable law.

6.9 ***Enforcement***. If any portion of this Agreement is determined to be invalid or unenforceable, such portion will be adjusted, rather than voided, to achieve the intent of the parties to the extent possible, and the remainder will be enforced to the maximum extent possible.

6.10 ***Conditions to Employment***. Notwithstanding anything to the contrary contained herein, this Agreement and the Executive's employment hereunder is subject to and conditioned on satisfactory background and reference checks, and on the Executive's provision of proof of his right to work in the United States.

6.11 ***Entire Agreement; Modifications***. Except as otherwise provided herein or in the exhibits hereto, this Agreement represents the entire understanding among the parties with

respect to the subject matter of this Agreement, and this Agreement supersedes any and all prior and contemporaneous understandings, agreements, plans, and negotiations, whether written or oral, with respect to the subject matter hereof, including, without limitation, any understandings, agreements, or obligations respecting any past or future compensation, bonuses, reimbursements, or other payments to the Executive from the Company. For clarity, this Agreement does not affect, alter, terminate or supersede any prior agreements related to grants of equity in Company, including grants of stock in Company and options to purchase stock in Company, except as, and to the extent, expressly provided herein. All modifications to the Agreement must be in writing and signed by each of the parties hereto.

6.12 ***Compliance with Section 409A***.

(a) Subject to this Section 6.11, any severance payments that may be due under this Agreement shall begin only upon the date of the Executive's "separation from service" (determined as set forth below) which occurs on or after the termination of the Executive's employment. The following rules shall apply with respect to distribution of the severance payments, if any, to be provided to the Executive under this Agreement, as applicable:

(1) It is intended that each installment of the severance payments under this Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Code and the guidance issued thereunder ("***Section 409A***"). Neither the Company nor the Executive shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.

(2) If, as of the date of the Executive's "separation from service" from the Company, the Executive is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in this Agreement.

(3) If, as of the date of the Executive's "separation from service" from the Company, the Executive is a "specified employee" (within the meaning of Section 409A"), then, except as otherwise permitted under Section 409A, any payments that would, absent this subsection, be paid within the six (6)-month period following the Executive's "separation from service" from the Company shall not be paid until the date that is six (6) months and one day after such separation from service (or, if earlier, the Executive's death), with any such installments that are required to be delayed being accumulated during the six (6)-month period and paid in a lump sum on the date that is six (6) months and one day following the Executive's separation from service and any subsequent installments, if any, being paid in accordance with the date and terms set forth herein.

(b) The determination of whether and when the Executive's "separation from service" from the Company has occurred shall be made in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Section 6.11(b), "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

(c) All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during the Executive's lifetime (or during a shorter period of time specified in this Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred, and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

(d) The Company makes no representation or warranty and shall have no liability to the Executive or to any other person if any of the provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A but do not satisfy an exemption from, or the conditions of, that section.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date.

Company:

/s/ Mark Augusti Date: 2/4/2020

Mark Augusti
Chief Executive Officer
Conformis, Inc.
600 Technology Park Drive
Billerica, MA 01821

Executive:

/s/ Robert Howe Date: 01-27-2020

Robert Howe

EXHIBIT A

EMPLOYEE CONFIDENTIAL INFORMATION, INVENTIONS AND NON-COMPETITION AGREEMENT

THIS EMPLOYEE CONFIDENTIAL INFORMATION, INVENTIONS AND NON-COMPETITION AGREEMENT (this "***Agreement***") confirms the agreement between the undersigned individual ("***Employee***") and Conformis, Inc., a Delaware corporation ("***Conformis***"). This Agreement is effective as of February 17, 2020 and is a material part of the consideration for Employee's employment and promotion by Conformis.

7. ***Proprietary Information***. Employee understands that Conformis possesses and will possess Proprietary Information which is important to its business. For purposes of this Agreement, "***Proprietary Information***" means all forms and types of business, financial, marketing, operations, research and development, scientific, technical, economic, manufacturing and engineering information, whether tangible or intangible, that relates to the present or potential businesses, products or services of Conformis (including any person or entity directly or indirectly controlled by or controlling Conformis, or in which any of the aforesaid have at least a fifty percent (50%) beneficial interest), including without limitation, inventions and ideas (whether or not patentable, copyrightable, or subject to protection as trademark or trade name), trade secrets, original works, disclosures, processes, systems, methods, techniques, improvements, formulas, procedures, concepts, compositions, drawings, models, designs, prototypes, diagrams, flow charts, research, data, devices, machinery, instruments, materials, products, patterns, plans, compilations, programs, sequences, specifications, documentation, algorithms, software, computer programs, source code, object code, know-how, databases, trade names, intellectual property, clinical data and clinical observations, costs of production, price policy and price lists and similar financial data, marketing and sales data, promotional methods, business, financial and marketing plans, technology and product roadmaps, product integration plans, information on strategic partnership and alliances, licenses, customer lists and relationship information, supplier lists and relationship information, employee and consulting relationship information, accounting and financial data, any and all other proprietary information or information which is received in confidence by or for Conformis from any other person irrespective of the medium in which such information is memorialized or communicated.

8. ***Conformis Materials***. Employee understands that Conformis possesses or will possess "Conformis Materials" which are important to its business. For purposes of this Agreement, "***Conformis Materials***" are documents or other media or tangible items that contain or embody Proprietary Information or any other information concerning the business, operations or future/strategic plans of Conformis, whether such documents have been prepared by Employee or by others. "Conformis Materials" also include, but are not limited to, laptops, cell phones, personal digital assistants (PDAs), blueprints, drawings, photographs, charts, graphs,

notebooks, customer lists, computer files, disks, drives, tapes or printouts, sound recordings and other printed, typewritten or handwritten documents, as well as samples, prototypes, models, products and the like. Any property situated on Conformis' premises and owned by Conformis, including laptops, notebooks, cell phones, PDAs, computer files, emails, disks, drives, and other storage media, filing cabinets or other work areas, are subject to inspection by Conformis personnel at any time with or without notice.

9. ***Treatment of Proprietary Information and Conformis Property***.

9.1 ***Relationship***. Employee understands that Employee's employment creates a relationship of confidence and trust between Employee and Conformis with respect to Proprietary Information. Employee further understands that the unauthorized taking of Conformis' Proprietary Information may result in a civil and/or criminal liability under applicable state or federal law, including without limitation an award for double the amount of Conformis' damages and attorneys' fees in the event of willful action.

9.2 ***Obligations Regarding Proprietary Information***. All Proprietary Information and all title, patents, patent rights, copyrights, mask work rights, trade secret rights, and other intellectual property and rights (collectively "***Rights***") in connection therewith are and will be the sole property of Conformis. Employee hereby assigns to Conformis any Rights Employee may have or acquire in such Proprietary Information. At all times, both during Employee's employment by Conformis and after his/her termination by Employee or by Conformis for any or no reason, Employee will keep in confidence and trust and will not use or disclose, lecture upon, or publish any Proprietary Information without the prior written consent of an officer of Conformis except as may be necessary and appropriate in the ordinary course of performing Employee's duties to Conformis. Employee will obtain Conformis' written approval before publishing or submitting for publication any material (written, verbal, or otherwise) that relates to Conformis and/or incorporates any Proprietary Information. Proprietary Information may be considered technical data that is subject to compliance with the export control laws and regulations of the United States or other countries, and Employee will comply with such laws. Notwithstanding the foregoing, it is understood that, at all such times, Employee is free to use information which is generally known in the trade or industry and which is rightfully received free of a confidentiality obligation, and nothing contained in this Agreement will prohibit Employee from disclosing to anyone the amount of Employee's own compensation.

9.3 ***Obligations Regarding Conformis Materials***. All Conformis Materials are and will remain the sole property of Conformis. During Employee's employment by Conformis, Employee will not remove any Conformis Materials from the business premises of Conformis or deliver any Conformis Materials to any person or entity outside Conformis, except as Employee is required to do in connection with performing the Employee's duties to Conformis. Immediately upon the termination of Employee's employment by Employee or by Conformis for any or no reason, or during Employee's employment if so requested by Conformis, Employee

will return all Conformis Materials, apparatus, equipment and other physical property, or any reproduction of such property, excepting only (i) Employee's personal copies of records relating to Employee's compensation; (ii) Employee's personal copies of any materials previously distributed generally to shareholders or stockholders of Conformis; and (iii) Employee's copy of this Agreement.

9.4 ***Third Party Information***. Employee recognizes that Conformis has received and in the future will receive from third parties their confidential or proprietary information, including but not limited to personally identifiable or health information, subject to a duty on Conformis' part to maintain the confidentiality of such information and, in some cases, to use it only for certain limited purposes. Employee owes Conformis and such third parties, both during the term of Employee's employment and thereafter, a duty to hold all such confidential or proprietary information in the strictest confidence and not to disclose it to any person, firm or corporation (except in a manner that is consistent with Conformis' agreement with the third party or as otherwise required by law) or use it for the benefit of anyone other than Conformis or such third party (consistent with Conformis' agreement with the third party).

10. ***Employee Inventions and Works of Authorship***.

10.1 ***Ownership and Assignment***. All Inventions (as defined below) will be the sole property of Conformis unless the Invention: (a) was developed entirely on Employee's own time without using any of Conformis' equipment, supplies, facilities, or trade secret information; (b) does not relate at the time of conception or reduction to practice of the Invention to Conformis' business, including, without limitation, patient-specific, patient-matched and patient-engineered orthopedic implants, instruments and surgical procedures, or its actual or reasonably anticipated research or development; and (c) does not result from any work performed by the Employee for Conformis. All such Inventions shall be immediately assignable to Conformis, and, notwithstanding any other documents evidencing assignment that may be executed, this Agreement shall operate to automatically and immediately assign any and all such Inventions. Employee hereby immediately assigns such Inventions and all Rights in them to Conformis. Such assignment shall be to the maximum extent allowed under applicable law.

For purposes of this Agreement, "***Inventions***" includes all improvements, inventions, designs, formulas, works of authorship, trade secrets, technology, computer programs, compositions, ideas, processes, techniques, know-how and data, whether or not patentable, made or conceived or reduced to practice or developed by Employee, either alone or jointly with others, during the term of Employee's employment, including during any period prior to the date of this Agreement. Employee hereby waives and quitclaims to Conformis any and all claims of any nature whatsoever which Employee now or may hereafter have for infringement of any proprietary rights assigned to Conformis. Employee acknowledges that all original works of authorship which are made by Employee (solely or jointly with others) within the scope of

employment and which are protectable by copyright are “works made for hire,” pursuant to United States Copyright Act (17 U.S.C., Section 101).

10.2 ***Disclosure of Inventions***. Employee promptly will disclose in writing to Employee’s immediate supervisor, with a copy to the President of Conformis, or to any other persons designated by Conformis, all Inventions. Employee also will disclose to the President of Conformis all things that would be Inventions if made during the term of Employee’s employment, but which were conceived, reduced to practice, or developed by Employee within six (6) months after the termination of Employee’s employment with Conformis, unless Employee can demonstrate that the Invention had been conceived and first reduced to practice by Employee following the termination of Employee’s employment with Conformis and without use of any Proprietary Information or Conformis Materials. Such disclosures will be received by Conformis in confidence (to the extent they are not assigned in this Section 4 and do not extend the assignment made in this Section 4). Employee will not disclose Inventions to any person outside Conformis unless requested to do so by an officer of Conformis. Employee will keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that may be required by Conformis) of all Proprietary Information developed by Employee and all Inventions made by Employee during the period of Employee’s employment at Conformis, which records will be available to and remain the sole property of Conformis at all times.

10.3 ***Further Assurances***. Employee will perform, during and after Employee’s employment, all acts deemed necessary or desirable by Conformis to permit and assist it, at Conformis’ expense, in obtaining, maintaining, defending and enforcing Rights with respect to such Inventions and improvements in any and all countries. Such acts may include, but are not limited to, execution of documents and assistance or cooperation in legal proceedings. Employee will execute such declarations, assignments, or other documents as may be necessary in the course of Invention evaluation, patent prosecution, or protection of patent or analogous property rights, to assure that title in such Inventions will be held by Conformis or by such other parties designated by Conformis as may be appropriate under the circumstances. Employee irrevocably designates and appoints Conformis and its duly authorized officers and agents, as Employee’s agents and attorneys-in-fact to act for and on Employee’s behalf and instead of Employee, to execute and file any documents and to do all other lawfully permitted acts to further the above purposes with the same legal force and effect as if executed by Employee.

10.4 ***Moral Rights***. Any assignment of copyright pursuant to this Agreement includes all rights of paternity, integrity, disclosure and withdrawal and any other rights that may be known as or referred to as “moral rights” (collectively, “***Moral Rights***”). To the extent such Moral Rights cannot be assigned under applicable law and to the extent the following is allowed by the laws in the various countries where Moral Rights exist, Employee hereby waives such Moral Rights and consents to any such action of Conformis that would violate such Moral Rights in the

absence of such consent. Employee will confirm any such waivers and consents from time to time as requested by Conformis.

10.5 ***Pre-Existing Inventions***. Employee has attached to this Agreement as Attachment A a complete list of all existing inventions or improvements to which Employee claims ownership as of the date of this Agreement and that Employee desires to specifically clarify are not subject to this Agreement, and Employee acknowledges and agrees that such list is complete. If disclosure of an item on Attachment A would cause Employee to violate any prior confidentiality agreement, Employee understands that Employee is not to list such in Attachment A but is to inform Conformis that all items have not been listed for that reason. A space is provided on Attachment A for such purpose. *If no such list is attached to this Agreement, Employee represents that Employee has no such inventions and improvements at the time of signing this Agreement.* Employee will not improperly use or disclose any proprietary information or trade secrets of any former employers or other third parties, if any, and Employee will not bring onto the premises of Conformis any unpublished documents or any property belonging to any former employers or other third parties unless consented to in writing by such employers or such other third parties. If, in the course of Employee's employment with Conformis, Employee incorporates a prior Employee-owned invention into a Conformis product, process or machine, Conformis is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicensees) to make, have made, modify, use and sell such prior invention for any and all purposes as Conformis determines in its sole discretion. Notwithstanding the foregoing, Employee agrees that Employee will not incorporate, or permit to be incorporated, prior inventions in any Inventions without Conformis' prior written consent.

11. ***Non-Competition and Non-Solicitation***.

11.1 ***Non-Competition During Employment***. Employee agrees that during the term of Employee's employment with Conformis, Employee shall not engage in any employment, business, or activity that is in any way competitive with the business or proposed business of Conformis, and Employee will not assist any other person or organization in competing with Conformis or in preparing to engage in competition with the business or proposed business of Conformis. The provisions of this section will apply both during normal working hours and at all other times including, but not limited to, nights, weekends and vacation time, while Employee is employed by Conformis.

11.2 ***Non-Competition After Employment***. Employee agrees that during the Non-competition Period (hereinafter defined), Employee shall not directly or indirectly, without the prior written consent of Conformis, either on Employee's own behalf or on behalf of any third party, compete with Conformis in the development, engineering, marketing, management, production, sale or distribution of Competitive Products (hereinafter defined) in the Territory (hereinafter defined). "***Non-competition Period***" shall mean the twelve (12)-month period commencing upon

termination of Employee's employment with Conformis ; provided that the period shall be extended for so long as Employee violates the non-competition obligation set forth herein and for any period(s) of time required for litigation to enforce its provisions. "***Competitive Products***" shall mean (a) any replacement or resurfacing implants for a knee joint or a hip joint and (b) patient-specific orthopedic products and services that are manufactured using, or that employ, a medical image for the purpose of performing medical or surgical procedures on a knee joint or a hip joint and (c) other products that fall within the research and development activities of Conformis at the time of Employee's termination. "***Territory***" shall mean anywhere in the world. Conformis and I mutually agree that the following consideration supports my promises, undertakings, and obligations under this Section 11.2 regarding post-employment non-competition: the Option and the RSU Award described in my Employment Agreement at Sections 3.3 and 3.4, which consideration I acknowledge and agree is adequate, fair, reasonable, and mutually agreed upon.

11.3 ***Non-solicitation; Non-interference***. Employee agrees that during the term of Employee's employment with Conformis and the Non-competition Period, Employee will not directly or indirectly, without the prior written consent of Conformis, either on Employee's own behalf or on behalf of any third party, (i) disrupt, damage, impair or interfere with the business of Conformis whether by way of interfering with or raiding Conformis' directors, officers, employees, agents, consultants, vendors, suppliers, and partners with which Conformis does business, or in any manner attempting to persuade, solicit, recruit, encourage or induce any such persons to discontinue their relationship with Conformis, or (ii) solicit, service, accept orders from, or otherwise have business contact with any customer or potential customer of Conformis with whom Employee had any contact during the one (1)-year period preceding Employee's termination of employment, if such contact could directly or indirectly divert business from or adversely affect the business of Conformis. However, this obligation will not affect any responsibility Employee may have as an employee of Conformis with respect to the bona fide hiring and firing of Conformis personnel.

11.4 ***Acknowledgement.*** Employee understands and recognizes that (i) during and as a result of Employee's employment by Conformis, Employee will acquire experience, skills and knowledge related to Conformis' business and will become familiar with Conformis' Proprietary Information; (ii) his/her working for a competitor of Conformis would lead to the inevitable disclosure of Conformis' Proprietary Information; (iii) the goodwill to which Employee may be exposed in the course of employment belongs exclusively to Conformis; (iv) in the course of Employee's employment with Conformis, customers and others may come to recognize and associate Employee with Conformis, its products and services, and that Employee will thereby benefit from Conformis' goodwill; and (v) if Employee were to engage in competition with Conformis, directly or indirectly, Employee would thereby usurp Conformis' goodwill.

11.5 ***Reasonableness.*** Employee acknowledges and agrees that because of the nature of Conformis' products, services and customers, because of Employee's position with Conformis

and because of the scope of Conformis' business, the restrictions contained in this Section 5 are reasonable and necessary for the protection of the business and goodwill of Conformis. If at any time the provisions of this Section 5 shall be deemed invalid or unenforceable or are prohibited by the laws of the jurisdiction where they are to be performed or enforced, by reason of being vague or overbroad in any manner, or for any other reason, such provisions shall be considered divisible and shall become and be immediately amended to include only such restrictions and to such extent as shall be deemed to be reasonable and enforceable by the court or other body having jurisdiction over this Agreement; and Conformis and Employee agree that the provisions of this Section 5, as so amended, shall be valid and binding as though any invalid or unenforceable provision had not been included herein.

12. ***No Conflict With Other Agreements***. Employee represents and warrants that (a) the performance of Employee's employment with Conformis and all the terms of this Agreement will not breach or conflict with any other agreement to which Employee is a party, including without limitation, any confidentiality agreement, nondisclosure agreement, non-competition and/or non-solicitation agreement, employment agreement, proprietary rights agreement or the like, (b) Employee will abide by all such agreements to the extent required by law, (c) Employee has delivered to Conformis a copy of all such agreements that may bear on Employee's employment with Conformis, and (d) Employee has not entered into, and will not enter into, any agreement either written or oral in conflict herewith or in conflict with Employee's employment with Conformis. If Employee is requested to perform any task on behalf of Conformis that would violate any outstanding obligations of any kind that Employee has to any of Employee's prior employers or third parties, Employee shall contact Conformis' human resources or legal departments as soon as possible to resolve the issue.

13. ***At Will Employment***. This Agreement is not a contract guaranteeing employment of a specified length, and each of Employee and Conformis has the right to terminate Employee's employment at any time, for any or no reason, with or without cause.

14. ***Termination Certificate***. Upon termination of Employee's employment by Employee or by Conformis for any or no reason, Employee will execute and deliver to Conformis a termination certificate substantially in the form attached to this Agreement as Attachment B.

15. ***Limitation of Application; Independent Agreement***. Employee acknowledges that (a) this Agreement does not purport to set forth all of the terms and conditions of Employee's employment and, as an employee of Conformis, Employee has obligations to Conformis which are not set forth in this Agreement, (b) this Agreement is a separate binding obligation independent of Employee's employment or continued employment by Conformis and (c) any breach or alleged breach by Conformis of any obligation to Employee of any nature shall not affect in any manner the binding nature of Employee's obligations under this Agreement and Employee WAIVES any defense based on any alleged material breach by Conformis of any of its

obligations to Employee in regard to any claim against Employee alleging breach of this Agreement.

16. ***Survival; Forwarding of Agreement***. This Agreement shall survive any and all changes in terms and conditions of Employee's employment with Conformis and any break in Employee's service or employment with Conformis. All of the provisions of this Agreement will continue in effect after termination of Employee's employment, regardless of the reason or reasons for termination, and whether such termination is voluntary or involuntary on Employee's part. Employee will notify any future client, employer or potential employer or client of Employee's obligations under this Agreement. Conformis is entitled to communicate Employee's obligations under this Agreement to any future employer or potential employer.

17. ***Equitable Relief***. Conformis has expended substantial efforts to maintain the confidentiality and proprietary nature of the information described in this Agreement and would be materially and irreparably injured by an unauthorized disclosure of any of that information. Any breach of this Agreement will result in irreparable and continuing damage to Conformis for which there can be no adequate remedy at law, and in the event of any such breach, Conformis will be entitled to immediate injunctive relief and other equitable remedies (without any need to post any bond or other security) in addition to such other and further relief as may be proper.

18. ***Disputes***. Any dispute in the meaning, effect or validity of this Agreement will be resolved in accordance with the laws of the Commonwealth of Massachusetts, without regard to its conflict of laws provisions. The exclusive venue for any disputes relating to this Agreement will be in Middlesex County, Massachusetts. The non-prevailing party in any dispute will pay the prevailing party's attorneys' fees and costs relating to such dispute.

19. ***Severability***. If one or more provisions of this Agreement are held to be illegal or unenforceable under applicable law, such illegal or unenforceable portion(s) will be revised to make them legal and enforceable. The remainder of this Agreement will otherwise remain in full force and effect and enforceable in accordance with its terms.

20. ***Assignment; Binding Nature***. Conformis may assign this Agreement, or any rights or obligations herein, in connection with the transfer or sale of all or substantially all of its assets or stock, without any consent of, or notice to, Employee to be effective. This Agreement will be binding upon Employee, Employee's heirs, executors, assigns, and administrators and will inure to the benefit of Conformis, its subsidiaries, successors and assigns.

21. ***Entire Agreement; Modification in Writing***. This Agreement contains the entire agreement and understanding between the parties hereto, and supersedes all prior and contemporaneous agreements, terms and conditions, whether written or oral, made by the parties hereto concerning the specific subject matter of this Agreement. This Agreement can only be modified by a subsequent written agreement executed by the Employee and an executive officer of Conformis.

22. ***Acknowledgement***. Employee acknowledges that this Agreement is a condition of Employee's employment with Conformis, and that Employee has had a full and adequate opportunity to read, understand and discuss with Employee's advisors, including legal counsel, the terms and conditions contained in this Agreement prior to signing hereunder.

[Remainder of Page Intentionally Left Blank]

I HAVE READ THIS AGREEMENT CAREFULLY AND UNDERSTAND AND ACCEPT THE OBLIGATIONS WHICH IT IMPOSES UPON ME WITHOUT RESERVATION. NO PROMISES OR REPRESENTATIONS HAVE BEEN MADE TO ME TO INDUCE ME TO SIGN THIS AGREEMENT. I SIGN THIS AGREEMENT VOLUNTARILY AND FREELY, IN DUPLICATE, WITH THE UNDERSTANDING THAT ONE ORIGINAL COUNTERPART WILL BE RETAINED BY CONFORMIS AND THE OTHER ORIGINAL COUNTERPART WILL BE RETAINED BY ME.

IN WITNESS WHEREOF, CONFORMIS AND I HAVE EXECUTED THIS EMPLOYEE CONFIDENTIAL INFORMATION, INVENTIONS AND NON-COMPETITION AGREEMENT AS OF FEBRUARY 17, 2020.

Employee's Signature

Type/Print Employee's Name

Address:

Fax Number:

E-mail:

AGREED TO:

CONFORMIS, INC.

By: _____

Name: _____

Title: _____

2721533v1/999-283

CONFORMIS, INC.
CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (this "***Agreement***") is effective as of February 17, 2020 (the "***Effective Date***"), by and between Conformis, Inc., a Delaware corporation (the "***Company***"), and Frederick W. Driscoll, an individual with an address listed on the signature page hereto (the "***Consultant***").

WHEREAS, the Company desires consulting and similar services relating to the Company's business and products; and

WHEREAS, the Consultant desires to contract with the Company to perform such services.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter recited, the sufficiency of which is hereby acknowledged, the parties agree as follows:

1. ***Scope of Work***. The Consultant will perform the services set forth in Exhibit A attached hereto (the "***Services***"). Any additions to or modifications of the Services will be set forth in writing and will be signed by both parties in advance of the Consultant performing such additional or modified Services. The performance of Services and the compensation for Services necessary to the completion of such additions or modifications will be governed by this Agreement unless otherwise described in a written agreement of the parties.

2. ***Term***. The Consultant will serve as a consultant to the Company for a period commencing on the Effective Date and concluding when terminated in accordance with Section 9 of this Agreement (the "Term").

3. ***Consulting Fees***. The Company agrees to pay the Consultant for the Services in accordance with the payment schedule set forth in Exhibit B attached hereto.

4. ***Documentation of Services and Payments***. The Consultant will include with all invoices submitted to the Company an itemization and description of all Services for which the Consultant requests compensation with reasonable specificity to allow the Company to adequately account for such Services. The Company will pay each undisputed invoice submitted hereunder within 30 days of receipt thereof.

5. ***Noninterference; Noncompetition***. Consultant shall abide by Sections 5.2–5.4 of the Employee Confidential Information, Inventions, Non-Competition, and Non-Solicitation Agreement by and between Company and Consultant having an effective date of October 23, 2019 (the "***Non-Compete Agreement***") which are incorporated herein by reference. For clarity, the "Restricted Period" described in Section 5.2 of the Non-Compete Agreement shall begin running as of the first day following Consultant's last day of employment with the Company.

6. ***Confidentiality***.

(a) ***Definition***. For purposes of this Agreement, "***Confidential Information***" means all non-public, confidential or proprietary information disclosed on or after the Effective Date by the Company (including any parent, subsidiary or affiliate of the Company, and any person or entity directly or indirectly controlled by or controlling the Company, or in which any of the aforesaid have at least a 50% interest) or its representatives to the Consultant relating to any of the Company's or a third party's technology and/or business including, without limitation, this Agreement, Inventions (as defined below), any other inventions, trade secrets, patents, ideas, licenses, research and development, software, or other intellectual property, manufacturing plans, operations, business plans, finance plans, financial information, marketing plans, customer information, information regarding vendors and suppliers, products, services, strategic partnerships, or other information of Company or a third party known to be confidential or proprietary, and/

or other information of Company or a third party that reasonably should be known to be confidential or proprietary. Confidential Information may be in any form, including, without limitation, oral, written, and/or electronic form, and further includes, for example, notes, compilations, reports, databases, summaries and other materials prepared by or for the Consultant that contain, are based on, or derived from, in whole or in part, Confidential Information. Confidential Information does not include information that the Consultant can document (a) is (through no improper action or inaction of the Consultant) generally known by the public, (b) is rightfully in the Consultant's possession or rightfully known by the Consultant prior to receipt by the Company and was not disclosed in violation of any restrictions regarding confidentiality, (c) became available to the Consultant rightfully from a third party, and was not disclosed in violation of restrictions on confidentiality, or (d) was or is developed independently by the Consultant without reference to or use of, in whole or in part, any Confidential Information. For clarity, the Non-Compete Agreement shall apply to Proprietary Information (as defined in the Non-Compete Agreement) received by Consultant prior to the Effective Date and nothing in this Agreement shall modify Consultant's obligations to the Company under the Non-Compete Agreement. Further, the parties agree that during the term of this Agreement, the Company shall not provide to Consultant, and Consultant shall not accept, any Confidential Information that is not related to patient-specific, patient-matched and/or patient-engineered orthopedic implants and instruments for the knee and hip.

(b) ***Nondisclosure***. The Consultant acknowledges that Confidential Information is of great value to the Company. Accordingly, the Consultant agrees to hold all Confidential Information in confidence and not disclose, use, copy, publish, summarize or, if applicable, remove from the premises of the Company any Confidential Information. Upon the expiration or termination of this Agreement, the Consultant agrees (i) to promptly deliver to the Company all papers, records, data, notes, drawings, files, documents, samples, devices, products, equipment and other materials, including copies and in whatever form, relating to the Company that the Consultant possesses or creates, whether or not confidential or proprietary, (ii) to not disclose, use, copy, publish, summarize or, if applicable, remove from the premises of the Company any Confidential Information, and (iii) to promptly execute and deliver to the Company the "Termination Certificate" attached hereto as Exhibit C.

7. ***Inventions and Original Works of Authorship***.

(a) ***Definition***. For purposes of this Agreement, "***Inventions***" means any and all ideas and discoveries, including, without limitation, inventions, trade secrets, original works of authorship, findings, reports, disclosures, processes, systems, methods, formulae, procedures, concepts, compositions, techniques, drawings, models, diagrams, flow charts, research, data, devices, machinery, intellectual property, instruments, materials, products, patterns, compilations, programs, techniques, sequences, designs, specifications, documentation, algorithms, software, computer programs, source code, object code and mask works, as well as improvements thereof or know-how related thereto, whether copyrightable or patentable or not, which are made by the Consultant, alone or in combination with others, (i) pursuant to, related to or resulting from the provision of Services or other tasks by the Consultant under this Agreement or any other agreement with the Company, or (ii), during the Term, that involve patient-specific, patient-matched and/or patient-engineered orthopedic implants, instruments and surgical procedures for the knee, hip, shoulder or ankle, or (iii) with the use of or as a result of access to Confidential Information, including, without limitation, any derivative work which constitutes an improvement or modification to any Confidential Information, such as any design, drawing, or product that embodies Confidential Information.

(b) ***Ownership and Assignment***. All Inventions are and shall be the sole and exclusive property of the Company and/or its nominees or assigns. Consultant hereby assigns to the Company any and all right, title and interest Consultant has, may have, or may acquire in all Inventions, and also all intellectual property rights relating thereto. To the extent that ownership of, or any rights to, any such Inventions does not immediately or automatically vest in the Company, the Consultant hereby assigns and agrees to assign to the Company or its designees, without further consideration, the Consultant's entire right, title, and interest in and to all such existing and future Inventions, including, without limitation, all rights to obtain, register, perfect, litigate, enforce and otherwise exploit inventions, patents, copyrights, trade secrets,

and other intellectual property rights and protections with respect thereto (whether or not patent or copyright applications are filed thereon). The Consultant will promptly notify the Company in writing of all Inventions so conceived or made by the Consultant. The Consultant shall have no license to or rights of any kind, including, including any such contractual rights or rights by operation of law, to any Inventions, unless explicitly granted by Company in writing in a separate agreement.

(c) ***Power of Attorney***. During the Term and as necessary thereafter, the Consultant will assist the Company (at the Company's expense) in performing any and all tasks and other actions reasonably necessary to obtain and enforce patents, copyrights, mask work rights, and other forms of intellectual property protection on Inventions, and to fulfill any and all related duties and obligations required by law. If the Company is unable because of the mental or physical incapacity of the Consultant or for any other reason to secure the signature of the Consultant to apply for or to pursue any application for any United States or foreign letters patent or copyright registrations covering Inventions assigned to the Company pursuant to Section 7(b), then the Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as the Consultant's agent and attorney in fact, to act for and on the Consultant's behalf and stead to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of letters patent or copyright registrations thereon.

(d) ***Moral Rights***. The Consultant also hereby irrevocably transfers and assigns to Company, and agrees to irrevocably transfer and assign to Company, and waives and agrees never to assert, any and all "Moral Rights" (as defined below) that the Consultant may have in or with respect to any Inventions, during and after the Term. "***Moral Rights***" mean any rights to claim authorship of any Invention, to object to or prevent the modification or destruction of any Invention, to withdraw from circulation or control the publication or distribution of any Invention, and any similar right, existing under judicial or statutory law of any country in the world, or under any treaty, regardless of whether or not such right is called or generally referred to as a "moral right."

(e) ***Patent Applications***. If the Company files an original United States patent application covering any invention of which the Consultant is a named inventor, the Consultant will receive an inventor's fee of $100.

(f) ***Further Assurances***. The Consultant will execute such documents as the Company will reasonably require to evidence and confirm the transfer of rights to the Company made under this Agreement.

8. ***Publishing***. As provided in Sections 6 and 7 above, data resulting from the Consultant's provision of Service pursuant to this Agreement, or the use of or access to Confidential Information, shall be an Invention owned by the Company and subject to confidential treatment. The Consultant shall not directly or indirectly (including, without limitation, by publication) disclose any such data or other Company Inventions or Confidential Information without the prior written consent of the Company. The Company shall have full editorial control with respect to any proposed publication by the Consultant that includes or makes reference to such data or other Company Inventions or Confidential Information (with the prior written consent of the Company), including without the limitation the rights to (a) not publish or make public such data or other Company Inventions or Confidential Information, (b) remove any such data or other Company Inventions or Confidential Information contained therein, and (c) protect its rights to any patentable Inventions set forth therein. As provided in Section 7 above, any such publication shall be an Invention owned by the Company.

9. ***Termination***. This Agreement will automatically terminate as stated in Exhibit A. In the event of any termination of this Agreement, the Company will make payments to the Consultant for all work performed in accordance with the terms and conditions of this Agreement up to the date of termination, and the Consultant will immediately return to the Company, without limitation, all documents, drawings and any other items of whatever nature supplied to the Consultant by the Company or owned by the Company pursuant to this Agreement.

10. ***Survival***. Each and all of the terms, provisions and/or covenants of each of Sections 5 through 22 of this Agreement will, for any and all purposes whatsoever, survive the termination of this Agreement.

11. ***Independent Contractor/Taxes***. Consultant is not an agent or employee of the Company and has no authority to act on behalf of the Company or to otherwise obligate or bind the Company by contract or otherwise. Except as required by a final determination by the Internal Revenue Service or state taxing authority and upon due notice to the other party, the Consultant and the Company agree to treat the Consultant as an independent contractor for tax purposes and to file all tax and information returns and pay all applicable taxes on that basis.

12. ***Third Party Contracts***. The Consultant represents that, other than with THINK Surgical, Inc., and except as disclosed in writing to the Company, (a) there are no other contracts to assign Inventions that are now in existence between any other party and the Consultant, and (b) the Consultant has no employments, consultancies or undertakings which would restrict or impair the Consultant's performance of this Agreement. The Consultant will not improperly use or disclose any proprietary information or trade secrets of any former or current employer or other third party. The Consultant will not bring onto the premises of the Company any unpublished documents or any property belonging to any former or current employer or other third party unless consented to in writing by such employer or such other third party. If, in the course of the Consultant's performance of this Agreement, the Consultant incorporates a prior Consultant-owned invention into a Company product, process or machine, the Company is hereby granted and will have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicensees) to make, have made, modify, use and sell such prior invention.

13. ***Assignment***. The rights and liabilities of the parties hereto will bind and inure to the benefit of their respective successors, assigns, heirs, executors and administrators, as the case may be; provided, however, that as the Company has specifically contracted for the Services to be provided by the Consultant hereunder, the Consultant may not assign or delegate the Consultant's obligations under this Agreement either in whole or in part without the prior written consent of the Company.

14. ***Governing Law; Consent to Jurisdiction***. This Agreement will be governed by, and construed in accordance with, the laws of the Commonwealth of Massachusetts, excluding those laws that direct the application of the laws of another jurisdiction. The Consultant hereby submits to the sole jurisdiction and venue of the courts of the Commonwealth of Massachusetts for purposes of any action or proceeding relating to this Agreement.

15. ***Injunctive Relief***. The Consultant acknowledges and agrees that damages will not be an adequate remedy in the event of a breach of any of the Consultant's obligations under this Agreement. The Consultant therefore agrees that the Company will be entitled (without limitation of any other rights or remedies otherwise available to the Company and without the necessity of posting a bond or other security) to obtain an injunction from any court of competent jurisdiction prohibiting the continuance or recurrence of any breach of this Agreement.

16. ***Headings***. The headings in this Agreement are intended principally for convenience and will not, by themselves, determine the rights and obligations of the parties to this Agreement.

17. ***Attorneys' Fees***. The prevailing party in any suit brought to enforce its rights under this Agreement will be entitled to reasonable attorneys' fees and costs.

18. ***Notices***. All notices, requests, demands, and other communications required by, or made in connection with, this Agreement or the transactions contemplated by this Agreement, will be in writing and will be deemed to have been duly given on the date of delivery, if delivered in person or by overnight mail carrier, or three business days after mailing if mailed by certified or registered mail, postage prepaid, return receipt requested, addressed as follows:

If to the Company: Conformis, Inc.
600 Technology Park Drive
Billerica, MA 01821
Attention: Chief Executive Officer

With a copy to:

Conformis, Inc.
600 Technology Park Drive
Billerica, MA 01821
Attention: Chief Legal Officer

If to the Consultant: The email address listed on the signature page hereto.

Such addresses may be changed, from time to time, by means of a notice given in the manner provided in this Section 18.

19. ***Severability***. If any provision of this Agreement is held to be unenforceable for any reason, such provision will be adjusted rather than voided, if possible, in order to achieve the intent of the parties to the maximum extent possible. In any event, all other provisions of this Agreement will be deemed valid and enforceable to the full extent possible.

20. ***Waiver***. The waiver of any term or condition contained in this Agreement by any party to this Agreement will not be construed as a waiver of a subsequent breach or failure of the same term or condition or a waiver of any other term or condition contained in this Agreement.

21. ***Counterpart and Facsimile Signatures***. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Agreement may be executed by facsimile signature (including signatures in Adobe PDF or similar format).

22. ***Entire Agreement; Modifications***. Except as otherwise provided herein or in the exhibits hereto, this Agreement represents the entire understanding among the parties with respect to the subject matter of this Agreement, and this Agreement supersedes any and all prior and contemporaneous understandings, agreements, plans, and negotiations, whether written or oral, with respect to the subject matter hereof, including, without limitation, any understandings, agreements, or obligations respecting any past or future compensation, bonuses, reimbursements, or other payments to the Consultant from the Company. For clarity, this Agreement does not modify or supersede the Non-Compete Agreement or the Amended and Restated Employment Agreement by and between Consultant and Company having an effective date of May 21, 2015, as amended from time-to-time. All modifications to the Agreement must be in writing and signed by each of the parties hereto.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have executed this Consulting Agreement as of the Effective Date.

Company: **Conformis, Inc.**

By: /s/ Mark A. Augusti
Mark A. Augusti
Chief Executive Officer

Consultant: /s/ Frederick W. Driscoll
Frederick W. Driscoll

Address: _____

_____

Telephone: _____

Email: _____

EXHIBIT A

SCOPE OF SERVICES

Upon written request by Company during the Term, the Consultant "***Services***" to the Company will include:

1. General consulting services as may be requested by the Company's Chief Executive Officer or Chief Financial Officer, or their designees, including, without limitation:
    a. providing transition services to the Company's new Chief Financial Officer and Finance team, in general.

The Consultant will report to the Company's Chief Financial Officer or his designee. The Consultant will provide Services at such place and times as the Company and the Consultant may mutually determine.

The Company will not control in any way the methods used by the Consultant in performing the Services.

This Agreement will automatically terminate on March 31, 2020. The parties hereto may extend the term of this Agreement by means of a written instrument executed by each of them, including in counterparts.

EXHIBIT B

CONSULTING FEES

The Company will pay the Consultant for Services rendered:

1. At the rate of $450.00 per hour.

2. Upon the expiration or termination of this Agreement on March 31, 2020, so long as the Consultant has rendered Services in good faith, and upon the Company's receipt of the executed Termination Certificate (Exhibit C), the total sum of $20,000.00.

The Company shall not be liable to pay any compensation for any Services that are not requested by the Company in advance.

Other than as set forth above, the Company will pay the Consultant no other compensation, whether in cash or non-cash form, for the Services.

EXHIBIT C

TERMINATION CERTIFICATE

This is to certify that I do not have in my possession, nor have I failed to return, any papers, records, data, notes, drawings, files, documents, samples, devices, products, equipment, designs, computer programs or other materials, including copies and reproductions of any of the aforementioned items, in whatever form, relating to Conformis, Inc. (the "***Company***"), whether or not confidential or proprietary.

I further certify that I have complied with all the terms of the Consulting Agreement by and between the Company and the undersigned dated as of February 17, 2020 (the "***Consulting Agreement***").

Moreover, I acknowledge and agree that, in compliance with the Consulting Agreement, I will hold in confidence and will not disclose, use, copy, publish, summarize or, if applicable, remove from the premises of the Company any "Confidential Information" (as defined in the Consulting Agreement).

Date: _____

Frederick W. Driscoll

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 2, 2020, with respect to the consolidated financial statements included in the Annual Report of Conformis, Inc. on Form 10-K for the year ended December 31, 2019. We consent to the incorporation by reference of said report in the Registration Statements of Conformis, Inc. on Forms S-8 (File No. 333-231211, File No. 333-229215, File No. 333-223802, File No. 333-217872 and File No. 333-2054777), and on Form S-3 (File No. 333-25464).

/s/ GRANT THORNTON LLP

Boston, Massachusetts
March 2, 2020

Exhibit 31.1

CERTIFICATIONS

I, Mark A. Augusti, certify that:

1. I have reviewed this Annual Report on Form 10-K of Conformis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: 3/2/2020

By: /s/ Mark A. Augusti
Mark A. Augusti
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Robert Howe, certify that:

1. I have reviewed this Annual Report on Form 10-K of Conformis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: 3/2/2020

By: /s/Robert Howe
Robert Howe
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Conformis, Inc. (the "Company") for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mark A. Augusti, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: 3/2/2020

By: /s/ Mark A. Augusti
Mark A. Augusti
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Conformis, Inc. (the "Company") for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert Howe, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: 3/2/2020

By: /s/Robert Howe
Robert Howe
Chief Financial Officer
(Principal Financial Officer)