

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

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2020

OR

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

Conformis, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

56-2463152

(I.R.S. Employer
Identification Number)

**600 Technology Park Drive
Billerica, MA**

(Address of principal executive offices)

01821

(Zip Code)

(781) 345-9001

(Registrant's telephone number, including area code)

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

Title of Each Class	Trading	Name of Each Exchange on Which Registered
Common Stock, \$0.00001 par value	CFMS	The Nasdaq Capital 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 every Interactive Data File required to be submitted 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 such files). Yes No

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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 Capital Market as of such date) was \$58,089,326. As of February 26, 2021 there were 182,578,964 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, 2020. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

Conformis, Inc.

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, our ability to raise additional funds, plans and objectives of management, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business 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, iTotals CR, iTotals PS, iTotals Identity, Conformis Hip System, and the planned launch of a new standard knee offering;
- 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;
- our ability to successfully develop and commercialize planned products;
- 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 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;
- anticipated continuing negative impacts related to the COVID-19 pandemic and the actions that we have taken and are planning in response, including our ability to continue production, the reliability of our supply chain, our ability to meet obligations and covenants under our loan agreements, the duration

- of decreased demand for our products, and whether or when the demand for elective surgery procedures will increase;
- our ability to satisfy all applicable NASDAQ continued listing requirements; and
- our ability to continue as a going concern.

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.

Risks Factors Summary

The following is a summary of the principal risk factors that make an investment in our common stock speculative or risky. Before you invest in our securities, you should read the following summary together with the more detailed description of material risks described under "Risk Factors" in Item 1A of this Annual Report and the other information contained in this Annual Report.

Risks related to our financial position.

- a. We have incurred losses in the past, expect to continue to incur losses in the future.
- b. Our existing and any future indebtedness could adversely affect our ability to operate our business.

Risks related to our business, industry and competitive position.

- a. We have derived nearly all of our revenue from sales of a limited portfolio of knee and hip replacement products to a small number of customers.
- b. We may not be successful in the development of, obtaining regulatory clearance for, or commercialization of, additional products.
- c. We face competition from large, well-established companies as well as new market entrants.
- d. We are deploying a new business model in an effort to disrupt a relatively mature industry.
- e. The success of our products is dependent on our ability to demonstrate their clinical benefits.
- f. We are subject to cost-containment efforts of, hospitals and other medical facilities and group purchasing organizations.
- g. Our revenues depend upon prompt and adequate coverage and reimbursement from public and private insurers and national health systems.
- h. 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 expected growth.
- i. We rely on a limited number of sales representatives and distributors to market and sell our products.

Global economic conditions may adversely affect our results of operations.

- a. The novel coronavirus (COVID-19) pandemic continues to adversely affect our business.
- b. Our sales and marketing depends on working relationships with R&D consultants and surgeons.
- c. Fluctuations in insurance cost and availability could adversely affect us.
- d. Consolidation in the healthcare industry could lead to demands for price concessions or the exclusion of some suppliers from certain of our markets.

Risks related to our manufacturing

- a. We may encounter manufacturing delays or problems or fail to meet certain regulatory requirements.
- b. We are dependent on third-party suppliers for important product components and essential services.
- c. We utilize a "just-in-time" manufacturing and delivery model with minimal inventory levels, leaving us vulnerable to delays or shortages of key components or materials, or product delivery delays.
- d. Our proprietary iFit software is critical to our business, and any delays in fixing bugs or errors and any limitations in our ability to modify such software for future products or modifications could hurt us.

Risks Related to Our Information Technology, Cybersecurity and Data Protection

- a. IT system management and implementation issues and security risks could disrupt our operations.
- b. A cybersecurity incident could result in confidential data loss or give rise to remediation and liabilities.

Risks related to our international operations

- a. Our international sales and operations expose us to various risks, including currency fluctuations.

Risks related to efforts to expand our growth

- a. We intend to grow our organization in accordance with our new long-range business plan, and as a result, we may encounter difficulties in managing our operations.
- b. Our success depends on our ability to retain, attract, retain and motivate officers and other personnel.

Risks related to our intellectual property and potential litigation

- a. We may not be able to obtain or protect proprietary rights relating to our products.
- b. We may be involved in lawsuits to protect or enforce our intellectual property rights.
- c. We license intellectual property rights from third parties under agreements that could be terminated.
- d. We may not be able to license additional intellectual property rights that we need for our business.
- e. Product liability lawsuits have been and may continue to be brought against.

Risks related to government regulation

- a. Our medical device products are subject to extensive U.S. and foreign governmental regulation.
- b. If our products, or malfunction of our products, contribute to a death or injury, we may face voluntary corrective actions or agency enforcement actions.
- c. We may be subject to voluntary or mandatory product recalls.
- d. Improper marketing or promotion of our products for which we have received regulatory clearance, approval, or certification could result in enforcement actions against us.

Risks related to other legal and compliance matters

- a. 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.
- b. Our relationships with healthcare providers, physicians and third-party payors will be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, in the event of a violation, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.
- c. Laws and regulations governing international operations may keep us from manufacturing and selling products outside of the U.S. and require us to develop and implement costly compliance programs.
- d. 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 penalties, litigation or regulatory investigations.
- e. Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

Risks related to our common stock

- a. We have issued substantially all of our available authorized shares of common stock.
- b. Our common stock could be delisted if we fail to maintain compliance with Nasdaq requirements.
- c. The price of our common stock can be volatile and fluctuate substantially.
- d. Our quarterly operating results are subject to substantial fluctuations.
- e. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
- f. Provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by stockholders to replace or remove current management.
- g. Exclusive forum provisions could discourage lawsuits against us and our directors and officers.
- h. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future.

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 \$19.5 billion annually and growing. 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. As of December 31, 2020, we had sold a total of more than 125,000 knee implants worldwide, including more than 100,000 total knee implants and 25,000 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 the second half of 2021, we plan to launch a new standard knee offering, which is being designed to provide a lower-cost alternative to hospitals, outpatient surgery centers, and ambulatory surgical centers (ASCs), while still taking full advantage of years of patient data collected through Conformis' unique business model. We are planning for a limited commercial launch of our cementless or Press Fit option for our iTotal Identity knee implant beginning during the fourth quarter of 2021 and/or first quarter of 2022, with the full commercial launch planned by the second half of 2022.

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. We are planning for a limited commercial launch of a second stem for the Conformis Hip System in the first half of 2022. In September 2020, we announced the new Cordera™ Hip System, and in December 2020, we commenced the U.S. commercial launch of the new Cordera™ Match Hip System, one of multiple planned product extensions featuring the Cordera™ 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 a September 2020 report from Beyond Compliance, results were presented summarizing six-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 1.6% for Conformis patients as compared with 2.4% for all total knee replacement patients. A clinical research study published online in July 2020 in *The Journal of Bone and Joint Surgery Reviews* found that the patients studied, who all received Conformis patient-specific iTotal PS (posterior-stabilized) knee replacement implants, were 90% satisfied, or very satisfied, 18–28 months post-surgery.

- **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, 2021, we own or exclusively in-license a total of approximately 349 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 159 issued United States patents, 131 patents issued in countries outside the United States, and 59 patent applications worldwide. See "Note H—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 CE Certificates of Conformity allowing us to affix the 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, Spain, Portugal, the Netherlands, Belgium, the Dutch Antilles, Suriname, Australia, Argentina, the United Arab Emirates, the Sultanate of Oman, Italy, San Marino, Poland 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 32.5 million people in the United States and 500 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 2019 calendar year, which was published in May 2020 by Orthoworld Inc., or the 2019 Orthoworld Report, worldwide sales of joint replacement products, including replacements for knees, hips, shoulders, elbows, wrists, ankles and digits outside of trauma, exceeded \$19.5 billion in 2019 and are expected to grow to approximately \$20.5 billion by the end of 2022.

The 2019 Orthoworld Report estimated that worldwide sales of knee replacement products totaled approximately \$9.3 billion and, according to SmartTRAK, the United States represented approximately 59% of total estimated worldwide sales of such products.

In 2019, according to the 2019 Orthoworld Report, worldwide sales of hip replacement products totaled approximately \$7.8 billion. According to SmartTRAK, the United States represented approximately 52% of the total estimated worldwide hip replacement sales. SmartTRAK estimates that primary total hip replacement implants accounted for approximately 66% of revenue of the 2019 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 2019 Orthoworld Report, the worldwide extremities joint replacement market was estimated at \$2.4 billion in 2019.

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 enables 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 ($p\leq 0.05$) 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 has 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 2022. We launched on a limited basis our next generation iTTotal CR Identity knee replacement implant in the second half of 2019 and are planning a full commercial launch for both the iTTotal CR and PS Identity knee replacement implants in the second half of 2021. We have put the development of the next generation of our iUni partial knee replacement system on hold in order to focus on an iTTotal cementless option for our iTTotal knee implant. We are planning for a limited commercial launch of our cementless or Press Fit option for our iTTotal Identity knee implant beginning during the fourth quarter of 2021 and/or first quarter of 2022, with the full commercial launch planned by the second half of 2022. In the second half of 2021, we plan to launch a new standard knee offering, which is being designed to provide a lower-cost alternative to hospitals, outpatient surgery centers, and ASCs, while still taking full advantage of years of patient data collected through Conformis' unique business model. 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, 2021, we own or exclusively in-license a total of approximately 349 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 H—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

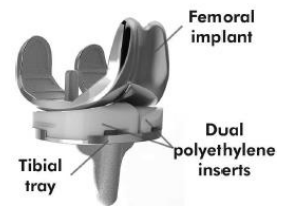
We offer a broad line of primary knee replacement implants, both partial and total, that we personalize through proprietary software and services to fit the individual patients. Surgeons use our family of personalized knee implants to treat mild to severe osteoarthritis of the knee. All of our knee replacement 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:

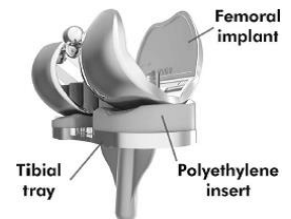
iTotal CR

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.



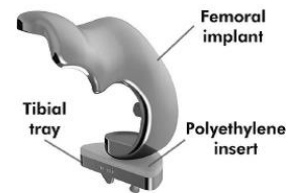
iTotal PS

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.



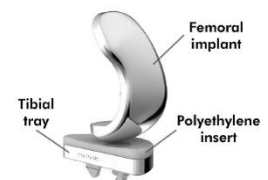
iDuo

The iDuo is the only personalized bicompartamental 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.



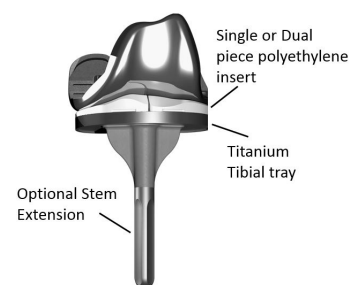
iUni

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.

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.

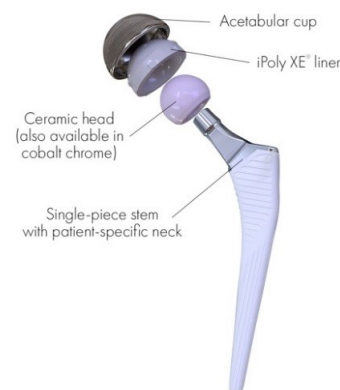
The following is an overview of our Conformis Hip System:

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, and FDA 510(k) clearance on September 24, 2020 for an expansion to the Cordera™ Hip System which may incorporate a personalized surgical plan and patient specific instruments. The Cordera Hip System, is an uncemented, primary total hip replacement composed of femoral and acetabular components. 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. In December 2020, we commenced the U.S. commercial launch of the new Cordera™ Match Hip System, one of multiple planned product extensions featuring the Cordera™ Hip System. The Cordera™ Match Hip System is implanted utilizing a surgeon-approved, personalized iView and patient-specific iJigs.

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, 2021, 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, Spain, Portugal, the Netherlands, Belgium, the Dutch Antilles, Suriname, Australia, Argentina, the United Arab Emirates, the Sultanate of Oman, Italy, San Marino, Poland and other markets. 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 40 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, 2020, and 2019, company-sponsored research and development expense was \$11.9 million, and \$12.5 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, Wallingford, Connecticut and Hyderabad, India.

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 verify that quality to specifications are met. 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 maintain certification by the British Standards Institution (BSI Netherlands), or BSI, a Notified Body, as required by the Medical Device Directives of Europe, to the International Standards Organization Standard 13485 of our quality system. Certification by a Notified Body to ISO 13485 constitutes a presumption of conformity with the related elements of the MDD and, in the future, the MDR, a necessary element of obtaining CE Marking in the EU. As a result of Brexit, BSI has established offices in Netherlands to continue to provide Notified Body CE Mark services for the Industry in Europe. We have moved our registrations to BSI Netherlands Office. 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 patent applications in the U.S. and certain foreign jurisdictions 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, 2021, we owned or exclusively in-licensed 290 issued patents around the world, including 159 patents issued in the United States and 131 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 2036.
- 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 2036.
- 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, 2021, we owned or exclusively in-licensed 59 patent applications, including 20 patent applications pending in the United States and 39 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 group of applications 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 2036. 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 I, 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 the right to receive up to an additional \$16 million in milestone payments under the License Agreement and the Development Agreement. As of December 31, 2020, we had completed two of three milestones set forth in the License Agreement and the Development Agreement and received \$5.0 million in the aggregate for achievement of these milestones. 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.

License and settlement agreement with Zimmer

On May 22, 2020, we entered into a Settlement and License Agreement, with Zimmer Biomet, Zimmer US, Inc. and Biomet Manufacturing, LLC, or collectively, Zimmer Biomet, pursuant to which the parties agreed to terms for resolving then existing patent disputes. Under the Settlement and License Agreement, we and Zimmer Biomet agreed to dismiss both outstanding patent infringement lawsuits between the parties, we granted to Zimmer Biomet a royalty-free, non-exclusive, worldwide license to certain of our patents for Zimmer Biomet's patient-specific instrumentation used with off-the-shelf knee, hip, and shoulder implants, and Zimmer Biomet granted us a fully paid-up, royalty-free, non-exclusive, worldwide license to certain Zimmer Biomet patents for our implants and patient-specific instruments for the knee. Under the agreement, Zimmer Biomet was required to pay us a total of \$9.6 million in installments through January 15, 2021, and all such payments were made and received by such date. No payment was due from us to Zimmer Biomet under the agreement.

Trademarks

As of January 31, 2021, we have filed 142 trademark registrations in the United States and in other major markets worldwide, including the following marks: Conformis, iFit, iTototal, 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 European Economic Area (EEA). 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, certificates of conformity from Notified Bodies in the EEA, 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), approval of a de novo application, or approved by the FDA pursuant to a premarket approval application, or PMA. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA 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 of 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. 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. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed.

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. After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

To date, none of our submissions to the FDA have required FDA review under the premarket approval process nor have any of our 510(k)s 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.

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;

- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing or delaying our requests for regulatory approvals or clearances of new products or modified products;
- withdrawing a PMA that has already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Regulation of medical devices in the EEA

The EU Medical Devices Directive (Council Directive 93/42/EEC), or the MDD, sets out the basic regulatory framework currently applicable to medical devices in the EEA. In the EEA, 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 CE Mark, to our medical devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements of the MDD and obtain the right to affix the CE mark, 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), in relation to which the manufacturer can

issue an EC 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 a Competent Authority of an EEA country to conduct conformity assessments, which is referred to as a Notified Body. The Notified Body would typically audit and examine products' technical documentation and the quality system for the manufacture, design and final inspection of the devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the Essential Requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These include the requirement of prior authorization by the Competent Authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming.

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. CE marking of our products currently involves a Notified Body. The Notified Body that has conducted conformity assessments with respect to our joint replacement products is BSI Netherlands.

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 EEA, 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 December 2, 2022 for our iUni product, May 26, 2024 for our iDuo product, and May 26, 2024 for our iTotal PS product. Our iTotal CR product CE Certificate of Conformity expires on May 8, 2021 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 documentation 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.

Moreover, in May 2017, the EU Medical Devices Regulation (Regulation 2017/745), or MDR was adopted. The EU Medical Devices Regulation repeals and replaces the MDD. Unlike directives, which must be implemented into the national laws of the individual EEA Member States, the Regulation will be directly applicable, i.e., without the need for adoption of national implement laws in the individual EEA countries, in all EEA countries and is intended to eliminate current differences in the regulation of medical devices among EEA countries. The MDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The MDR will become applicable on May 26, 2021. Once applicable, the new Regulation will among other things:

- strengthen the rules on placing devices on the EEA market and reinforce surveillance once they are available;
- establish explicit provisions concerning manufacturers' responsibilities for follow-up to ensure the on-going quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EEA;
- strengthened rules for the assessment of certain high-risk devices which may have to undergo an additional check by experts before they are placed on the market.

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 European Commission and the Competent Authorities of EEA countries, 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 within the Company. 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 2021.

UK and Brexit

The UK's withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the UK and the EU. On December 24, 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU-UK Trade and Cooperation Agreement. The Agreement primarily focuses on ensuring free trade between the EU and the UK in relation to goods. The Agreement does not however, specifically address medical devices. The Agreement seeks to ensure that the parties ensure "regulatory cooperation". Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules. In light of the fact that the CE marking process is set out in EU law, which no longer applies in the UK, the UK has devised a new route to market culminating in a UK Conformity Assessed (UKCA) mark to replace the CE mark. Northern Ireland will, however, continue to be covered by the regulations governing CE marks. As part of the Agreement, the EU and the UK have agreed to continue to recognize declarations of conformity based on a self-assessment in the other territory.

The UK Medicines and Healthcare Products Regulatory Agency (MHRA) has issued Guidance on Regulating medical devices in the UK. This Guidance provides that the MHRA continue to recognize CE marking in Great Britain until June 30, 2023 and certificates issued by Notified Bodies designated in the EEA will continue to be valid for the Great Britain market until June 30, 2023. From July 1, 2023, manufacturers must obtain the UKCA mark, to place a medical device on the Great Britain market manufacturers must register their devices with the MHRA via the Device Online Registration System, subject to grace periods depending on the device classification. Manufacturers are required to designate an Authorized Representative in the UK and we have designated MDSS as our Authorized Representative in the UK and the EU. A UK designated Notified Body will be also be required for placing our devices on the market in the UK and we have designated BSI UK as our Notified Body in the UK and BSI Netherlands in the EU.

Marketing and sales considerations in the EEA and the UK

In the EEA and the UK, medical devices may be promoted only for the intended purpose for which the devices have been CE Marked. The advertising and promotion of our products in the EEA is subject to EEA countries' national laws implementing the MDD and, in the future, applying the MDR. Moreover, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as national legislation of individual EEA countries governing the advertising and promotion of medical devices also apply. EEA countries' legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EEA and national industry Codes of Conduct provide guidelines

on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

Failure to comply with this requirement could lead to the imposition of penalties by the Competent Authorities of EEA countries and the UK. The penalties could include warnings, orders to discontinue the promotion of the medical device, seizure of the promotional materials and fines.

Product vigilance and post-approval monitoring in the EEA and the UK

Additionally, all manufacturers placing medical devices on the market in the EEA and the UK are legally bound to report certain incidents involving devices they produce or sell to the Competent Authority, in whose jurisdiction the incident occurred and to their Notified Body. Under the MDD, an incident is defined as any malfunction or deterioration in the characteristics and/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.

In the EEA and the UK, manufacturers must comply with vigilance reporting requirements. Incidents must be reported to the relevant Competent Authorities of the EEA countries or the MHRA in the UK. 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 outside the United States, 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 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 the EEA, 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 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 each of the years ended December 31, 2020 and 2019, sales in Germany represented 10% of our total product sales. 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.

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 (AKS) 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, lease, order or arranging for the purchase, lease, or order 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. This statute has been interpreted broadly to apply to arrangements between device manufacturers and prescribers, purchasers, formulary managers, and others. The term "remuneration" has been broadly interpreted to apply to anything of value including, for example, gifts, cash payments, donations, waivers of payment, ownership interests, and providing any item, service, or compensation for something other than fair market value. Liability under the AKS may be established without proving actual knowledge of the statute or specific intent to violate it. Although there are a number of statutory exceptions and regulatory safe harbors to the AKS protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration to those who prescribe, purchase, or recommend medical device products, including certain discounts, or engaging such individuals as consultants, advisors and speakers, may be subject to scrutiny if they do not fit within an exception or safe harbor. Moreover, there are no safe harbors for many common practices, such as educational grants and reimbursement support programs. Violations of this law are punishable by up to ten years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs.
- The federal civil False Claims Act (FCA) imposes liability, and provides for 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 of government funds, knowingly making, using, or causing to be made or used a false statement or record material to an obligation to pay money to the government, or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Manufacturers have faced liability under the FCA for providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the AKS also are deemed false or fraudulent claims for purposes of the FCA. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false or fraudulent claim or statement for violations, as well as exclusion from participation in federal healthcare programs.
- The federal Health Insurance Portability and Accountability Act of 1996, and its implementing regulations (collectively, HIPAA), imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement or representation, or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items, or services;
- We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA - other than with respect to providing certain employee benefits - we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or

disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA;

- The federal Physician Payments Sunshine Act requires applicable manufacturers of devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; 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. Several states have enacted legislation requiring medical device manufacturers to, among other things, establish marketing compliance programs; file periodic reports with the state, including reports on gifts and payments to individual health care providers; and/or register their sales representatives. Some states prohibit certain sales and marketing practices, including the provision of gifts, meals, or other items to health care providers.

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. The FDA has also begun enforcing its Cybersecurity Guidance Document through the review of 510(k) applications to ensure companies are addressing concerns around this issue. Lack of proper documentation on Cybersecurity may delay approval of a 510(k) or withdrawal of a 510(k).

EU Data Protection Legislation

The EU, EEA countries and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. The EU General Data Protection Regulation, or GDPR, became applicable on May 25, 2018 and is directly applicable in each EEA country. It is hoped that the Regulation will result in a more uniform application of data privacy laws across the EEA. The GDPR imposes strict requirements and onerous accountability obligations on companies that process personal data, especially if they process sensitive personal data (such as data concerning patient health), including significant fines for non-compliance with the GDPR. Implementation of the GDPR has influenced other jurisdictions to either amend, or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 27, 2018, California adopted the California Consumer Privacy Act of 2018, or CaCPA. CaCPA has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions in the GDPR.

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 L—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, 2021, we had 259 full-time employees, 31 of whom were engaged in sales and marketing, 41 in research and development, 115 in manufacturing and service, 38 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 key human capital objectives in managing our business include attracting, developing and retaining top talent while integrating diversity, equity and inclusion principles and practices into our core values.

We strive to attract a pool of diverse and exceptional candidates and support their career growth once they become employees. Our efforts begin at the entry level with development, including partnering with two- and four-year colleges and universities. We also emphasize in our evaluation and career development efforts internal mobility opportunities for employees to drive professional development for every employee, which we believe also drives our retention efforts.

We believe that our ability to retain our workforce is dependent on our ability to foster an environment that is sustainably safe, respectful, fair and inclusive of everyone and promotes diversity, equity and inclusion inside and outside of our business. Our key human capital objectives in managing our business include attracting, developing and retaining top talent while integrating diversity, equity and inclusion principles and practices into our core values.

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, proxy statement filings, 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 \$24 million for the year ended December 31, 2020, and \$28 million for the year ended December 31, 2019. As of December 31, 2020, we had an accumulated deficit of \$528 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. 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.

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

We are party to a Loan and Security Agreement with Innovatus Life Sciences Lending Fund I, LP (“Innovatus”), as collateral agent and lender, East West Bank and other lenders party thereto (collectively, the “Lenders”), pursuant to which the Lenders agreed to make term loans and to provide a revolving credit facility to the Company in a principal amount of up to \$30 million (the “2019 Secured Loan Agreement”). As of the date hereof, approximately \$20.0 million remains outstanding under the 2019 Secured Loan Agreement. 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 Secured Loan Agreement contains certain covenant requirements, including an ongoing 6-month trailing revenue covenant. Under the amended terms of the 2019 Secured Loan Agreement, the trailing 6-month revenue covenant milestones that applied to the quarters ended June 30, September 30, and December 30, 2020 were waived, as were the milestones that applied to the quarters ending March 31, June 30, September 30 and December 31, 2021, however, the revenue covenant and milestones remain in effect for periods thereafter. For further information regarding the 2019 Secured Loan Agreement, see “Note I—Debt and Notes Payable” 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 and hip replacement products and may not be able to maintain or increase revenue from these products. A substantial portion of our revenue is derived from a small number of customers.

To date, we have derived nearly all of our revenue from sales of our knee replacement products and 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 were required to conduct clinical studies or obtain clinical data to obtain future regulatory clearances or approvals for any of our products in the United States or elsewhere, the results of such studies might not be sufficient to support such regulatory clearance, approval, or certification. In addition, our costs of developing and the time to develop our products would increase significantly. Moreover, even if we obtain regulatory clearance, approval, or CE Certificates of Conformity to market a product, the FDA, in the United States, or a Notified Body, in the EEA, 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 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, clearances, or certifications outside of the United States 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, approval, or certification 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, thereby reducing our sales. 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, published between 2016 and 2018, in which our product did not perform as well as off-the-shelf products on some measures. Though we believe that these studies were of limited statistical significance given the limited investigations contained therein, these results could call into question the superiority of our products to traditional products.

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. Though initial six-year data from the England and Wales National Joint Registry suggests slightly higher survivorship in patients treated with the iTotal CR knee replacement implant, 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, our Notified Body and the Competent Authorities of EEA countries 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. 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.

Even if our products are approved or cleared in the United States and CE marked in the EEA, comparable regulatory authorities of additional foreign countries must also approve the manufacturing and marketing of our products in those countries. Approval, clearance and certification procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States or the EEA, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, financial condition and prospects significantly.

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.

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, 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.

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 EEA, 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. The COVID-19 pandemic has made it more difficult to train surgeons in-person on our products. It has also encouraged surgeons to explore virtual training options which require significant investment on behalf of the company and may not be as effective as in-person training.

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. 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 outside the United States, if the FDA, or other similar Competent Authorities outside the United States 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.

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.

The novel coronavirus (COVID-19) pandemic and the response to it have reduced demand for our products, and as a result we reduced our operations and production capacity, and these circumstances have had and are expected to continue to have a significant negative affect on our revenue.

Our business continues to be negatively affected by the ongoing COVID-19 pandemic. We have experienced significantly decreased demand for our products during the pandemic as healthcare providers and individuals have de-prioritized and deferred medical procedures deemed to be elective, such as joint replacement procedures, which has had and is expected to continue to have a significant negative effect on our revenue. Within the U.S. and Germany, which are our major sales markets, estimated case counts have increased since November 2020, though cases have begun to substantially decline again in recent weeks. While elective surgery sites generally remain open and operational, we believe that the increased hospital burden has negatively impacted surgical demand and capacity, temporarily delaying many procedures. In addition, there are concerns about future strains of COVID-19. We expect that these negative effects will continue in the near-term until infection rates decline from their current level, and more of the country's population is vaccinated. However, the future progression of the pandemic remains uncertain.

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, and equivalent laws of foreign countries requiring us to disclose payments or other transfers of value, such as free gifts or meals, to physicians and other healthcare providers could have a chilling effect on these relationships with individuals or entities that may, among other things, want to avoid public scrutiny of their financial relationships with us. In addition, consultants, surgeons and medical personnel in hospitals and universities may be subject to conflict of interest policies that limit our ability to engage these individuals as our advisors and in connection with future development and training efforts. If we are unable to establish and maintain our relationships with consultants, surgeons and medical personnel, our ability to develop and sell new and improved products could decrease, and our future operating results could be unfavorably affected.

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

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, business interruption insurance, property insurance and workers' compensation insurance. The cost of

maintaining product liability insurance on implantable medical devices has increased substantially over the past few years and could continue to substantially increase, due to general market trends, as part of an evaluation of our specific loss history and other factors. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating expenses could substantially increase, or we might need to operate our business without indemnity from commercial insurance providers.

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

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and may 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. This 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 or organizations such as Notified Bodies for the EEA. 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 used as a limited, alternative sterilization method for a small quantity of products. In response to the warning letter, we decommissioned the VHP sterilizers and completed all appropriate process and/or equipment validations of our manufacturing processes for implant components and instrumentation manufactured at our 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.

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 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.

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.

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. 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 2018, we continued transitioning our CAD labor force through a third-party CAD-designer in India and significantly reduced our CAD labor force in-house. In the fourth quarter of 2020, we established a new Conformis entity in India, Conformis India LLP, and plan to transition a portion of the third-party CAD design activities to Conformis India LLP. 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.

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.

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.

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.

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.

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, Spain, Portugal, the Netherlands, Belgium, the Dutch Antilles, Suriname, Australia, Argentina, the United Arab Emirates, the Sultanate of Oman, Italy, San Marino, Poland and other markets. We expect that our international activities will increase over the foreseeable future as we continue to pursue opportunities in additional international markets. 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.

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.

Risks related to efforts to expand our growth

We intend 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 third quarter of 2020 we announced our planned portfolio expansion and a new long-range business plan (LRP). Managing the business in accordance with the LRP has and will require significant attention by our management and we may be unable to successfully execute the LRP, which would negatively impact our ability to achieve our financial targets and could require us to seek additional financing.

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

Our future success depends on our ability to retain our 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.

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. 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 could be expensive and time consuming and could divert management's attention from managing our business.

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. 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 outside the United States 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.

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.

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.

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 variation 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, approvals or certification for our products and indications or if clearances, approvals or certification 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, a de-novo authorization 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. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. 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. If we conduct clinical trials, they may be delayed or halted or may be inadequate to support approval or clearance, for numerous reasons. 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.

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. Modifications to our 510(k) cleared products may require new regulatory approvals or clearances, including 510(k) clearances or approval of PMA supplements, or require us to recall or cease marketing the modified systems until these clearances or approvals are obtained. The FDA requires device manufacturers to

initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the product as modified, which could require us to redesign and/or seek new marketing authorizations and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a new PMA or approval of a PMA supplement. Where we determine that modifications to our cleared products require a new 510(k) clearance or PMA approval, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time-consuming process, and delays in obtaining required 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 future growth.

In the EEA, we are required to comply with applicable medical device directives (including the Medical Devices Directive and, from May 26 2021, the Medical Device Regulation, or MDR and obtain CE Certificates of Conformity in order to affix the CE mark and market medical devices. The CE Mark is applied to our products 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, then carry out a clinical evaluation of its medical device and prepare a Clinical Evaluation Report to demonstrate conformity with the relevant Essential Requirements.

Any delay in, or failure to receive or maintain, clearance, approval or certification for our products under development could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA, Competent Authorities of EEA countries, and other regulatory authorities outside the United States 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 CE Certificates of Conformity to sell our product in the EEA, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products in the EEA. We must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearances or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. The withdrawal of or variation in a CE Certificate of Conformity and the recall or withdrawal of our product from the market in the EEA 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, commonly three years.

Legislative or 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.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

The FDA's and other foreign regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance, approval or certification of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, the recent change in administration may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these executive actions will be implemented, or whether they will be rescinded or replaced under the current Biden administration. The policies and priorities of a new administration are unknown and could materially impact the regulation governing our products.

Any change in the laws or regulations that govern the clearance, approval, and certification processes relating to our current, planned 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. Significant delays in receiving clearance, approval, or certification or the failure to receive clearance, approval or certification for any new products would have an adverse effect on our ability to expand our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing clearance that we may have obtained and we may not achieve or sustain profitability.

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"), 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.

In the EU, Regulation (EU) 2017/745, the Medical Devices Regulation or MDR, will enter into application on May 26, 2021. The Regulation will introduce substantial changes to the obligations with which medical device manufacturers must comply in the EEA. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. Specifically, the MDR repeals and replaces the MDD. Unlike directives, which

must be implemented into the national laws of the EEA Member States, the Regulation will be directly applicable, i.e., without the need for adoption of related individual national implementing laws by EEA countries. It is intended to eliminate current differences in the regulation of medical devices among EEA countries. The MDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. Once applicable, the Medical Devices Regulation will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices which may have to undergo an additional check by experts before they are placed on the market.

It will be necessary for Notified Bodies to be designated by the EEA countries Competent Authorities to conduct conformity assessment procedures for medical devices in accordance with the MDR. There are currently a relatively small number of notified bodies that have been designated to conduct these assessments. This may delay conformity assessment procedures in the future in the EEA.

Once applicable, the MDR may impose increased compliance obligations for us to access the EEA market. Complying with the requirements of this regulation may require us to incur significant expenditures.

In order to continue to sell our products in the EEA, we must maintain our CE marks and continue to comply with the MDD and, beginning in May 2021, with the MDR. The new requirements imposed on manufacturers of medical devices by the MDR may impact our activities in the EEA, the renewal of our existing CE Certificates of Conformity and conformity assessment processes.

Our failure to continue to comply with applicable regulatory requirements, including those administered by the Competent Authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our Notified Body, which could impair our ability to market products in the EEA in the future.

Any changes to the membership of the EU, such as the recent departure of the United Kingdom (Brexit), may impact the regulatory requirements imposed by the relevant countries and impair our business operations and our ability to market products in such countries.

The UK's withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the UK and the EU. On December 24, 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU-UK Trade and Cooperation Agreement. The Agreement primarily focuses on ensuring free trade between the EU and the UK in relation to goods. The Agreement does not however, specifically address medical devices. The Agreement seeks to ensure that the parties ensure "regulatory cooperation". Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules. In light of the fact that the CE marking process is set out in EU law, which no longer applies in the UK, the UK has devised a new route to market culminating in a UK Conformity Assessed (UKCA) mark to replace the CE mark. Northern Ireland will, however, continue to be covered by the regulations governing CE marks. As part of the Agreement, the EU and the UK have agreed to continue to recognize declarations of conformity based on a self-assessment in the other territory. Given the lack of comparable precedent to Brexit, it is unclear what the financial, regulatory, and legal implications of Brexit will be and how it will affect us. However, potentially changing regulatory schemes and tariffs engendered by Brexit may add additional complexity, cost and delays in marketing or selling our products in the United Kingdom. Our revenue and profit, supply and demand for our products, and customer retention and acquisition in both the long term and short term could be adversely affected.

Modifications to our currently FDA-cleared products or the introduction of new products may require new regulatory clearances or approvals or equivalent steps in third countries including the EEA 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.

For those products sold in the EEA, we must notify our Notified Body if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Obtaining certification can be a time-consuming and expensive process, and delays in obtaining required future certification would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Our cleared, approved and CE marked 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, approval, or CE Certificates of Conformity 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, Competent Authorities of EEA countries, notified bodies and other foreign 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, or equivalent foreign authorities, 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 or equivalent foreign laws caused by the device that may present a risk to health, and maintain records of other corrections or removals. If we receive regulatory clearance, approval, or CE Certificates of Conformity for 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, approval, or CE Certificates of Conformity and the accompanying label may limit the approved use of our product, which could limit sales of the product.

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.

If we or our suppliers fail to comply with ongoing FDA, EEA 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, approval, or CE Certificates of Conformity 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 and notified bodies. In particular, we and most of our third-party suppliers are required to comply with the FDA's Quality System Regulation, or QSR, in the US, and the applicable regulatory requirements in the EEA 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

MDD and MDR, 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, in the US, 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 used as a limited, alternative sterilization method for a small quantity of products. We have responded to all observations in both the Form 483s and the warning letter, including by decommissioning the VHP sterilizers in October 2020 and conducting revalidations. We continue to take various corrective and preventative actions to improve our quality, production and design control systems; nevertheless, we cannot be certain 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 Netherlands, an independent 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 MDD and MDR.

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 EEA, 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 EEA 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 EEA, 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 EEA Member States, 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. Under the MDD, 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 incident 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. Incidents involving our products have been reported to us in the past, and similar adverse events may occur in the future. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. 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, Competent Authorities of EEA countries 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, voluntarily 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. Competent Authorities of foreign countries impose similar deadlines.

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 or to the Competent Authorities of foreign countries. If the FDA or the Competent Authorities of foreign countries disagree 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 or the Competent Authorities of foreign countries could take enforcement action for failing to report the recalls when they were conducted.

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, approval, or CE Certificates of Conformity. 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.

The advertising and promotion of our products in the EEA is subject to the national laws of the individual EEA countries implementing the MDD and, in the future, applying the MDR. Moreover, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EEA countries governing the advertising and promotion of medical devices govern our advertising and promotional activities. EEA countries' legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

In the EEA, 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 national Competent Authorities of EEA countries. 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 EEA 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.

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.

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, lease, order or recommendation or arranging of the purchase, lease, or order of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- The federal civil False Claims Act imposes 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 of government funds, or making or causing a false statement or record material to a false or fraudulent claim or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus significant mandatory penalties per false claim or statement for violations for each separate false claim, and the potential for exclusion from participation in federal healthcare programs.

- The federal Health Insurance Portability and Accountability Act of 1996, and its implementing regulations, (collectively, HIPAA), imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document in connection with the delivery of or payment for health care benefits, items, or services.
- We may obtain health information from third parties that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA - other than with respect to providing certain employee benefits - we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.
- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians, teaching hospitals, and other healthcare providers, as well as ownership interests held by physicians and their immediate family members. Annual reporting of such transfers of value by manufacturers has increased scrutiny of the financial relationships between industry and the physicians, teaching hospitals and other healthcare providers. Failure to submit required annual information may result in civil monetary penalties, which may increase significantly for “knowing failures.”
- 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.

For further details about the scope and requirements of these laws, please see *Part I, Item 1.- Business - Healthcare laws and regulations*.

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, and exclusion from participation in federal healthcare programs such as Medicare and Medicaid. 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.

We may be subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy and/or genetic privacy laws and federal and state consumer protection laws, (e.g., Section 5 of the FTC Act and the California Consumer Privacy Act (CCPA)), govern the collection, use, disclosure, and protection of health-related and other personal information. Many of these laws differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant civil or criminal penalties), private litigation and/or adverse publicity that could negatively affect our business. Federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space.

In particular, HIPAA imposes requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA - other than with respect to providing certain employee benefits - we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

The CCPA establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The CCPA and its implementing regulations have already been amended multiple times since their enactment. Similarly, there are a

number of legislative proposals in the United States, at both the federal and state level, that could impose new obligations or limitations in areas affecting our business. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. The obligations to comply with the CCPA and evolving legislation may require us, among other things, to update our notices and develop new processes internally and with our partners. We may be subject to fines, penalties, or private actions in the event of non-compliance with such laws.

The legislative and regulatory landscape for privacy and data security continues to evolve. There has been increased attention to privacy and data security issues that could potentially affect our business, including the EU General Data Protection Regulation, which entered into effect on May 25, 2018 and imposes penalties up to 4% of annual global turnover. In addition, laws and regulations enacted in the United States, Europe, Asia and Latin America, including the new California Consumer Privacy Act of 2018, which went into effect January 1, 2020, increases potential enforcement and litigation activity. Because of this, we may need to engage in additional compliance efforts, including data mapping to identify the personal information we are collecting and the purposes for which such information is collected and enhanced consumer controls with respect to their data.

In the event we enroll subjects in our ongoing or future clinical trials in the EEA, we may be subject to additional privacy restrictions, including restrictions relating to the collection, use, storage, transfer, and other processing of personal data, including personal health data, regarding individuals in the EEA as governed by the General Data Protection Regulation, or GDPR. The GDPR imposes several requirements on companies that process personal data, strict rules on the transfer of personal data out of the EEA, including to the U.S and fines and penalties for failure to comply with the requirements of the GDPR and the related national data protection laws of the individual EEA countries. The GDPR also confers 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. The obligations under the GDPR may be onerous and adversely affect our business, financial condition, results of operations and prospects. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any EEA activities. Further, the United Kingdom's exit from the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom.

Because of the remote work policies we implemented due to the COVID-19 pandemic, information that is normally protected, including company confidential information, may be less secure. Cybersecurity and data security threats continue to evolve and raise the risk of an incident that could affect our operations or compromise our business information or sensitive personal information, including health data.

We may also need to collect more extensive health-related information from our employees to manage our workforce. If we or our third party partners fail to comply or are alleged to have failed to comply with applicable data protection and privacy laws and regulations, and related employment rules, or if we were to experience a data breach involving personal information, we could be subject to government enforcement actions or private lawsuits.

In addition, our business could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results. For example, in July 2020, the Court of Justice of the European Union, or the Court of Justice, declared the Privacy Shield Decision (Decision 2018/1250) invalid, which could adversely impact our ability to transfer personal data from the EU to the U.S. The Court of Justice further ruled that in order to transfer data outside of the EU, under the existing mechanism known as the Standard Contractual Clauses, or SCCs, the importing country's level of protection must be adequate.

On September 8, 2020, the Federal Data Protection and Information Commissioner, or FDPIC, of Switzerland issued an opinion concluding that the Swiss-U.S. Privacy Shield Framework does not provide an adequate level of protection for data transfers from Switzerland to the United States. The FDPIC also found that SCCs may still be legally adequate at an individual level provided that they can pass a risk assessment conducted by the FDPIC. If the level of protection in the U.S. or any other importing country is called into question under the SCCs, this could further impact our ability to transfer data outside of the EU or Switzerland.

If we or any of our service providers are found to be in violation of HIPAA, the GDPR, or other data protection laws in the U.S. or internationally, we could be subject to government enforcement actions, civil and/or criminal penalties, litigation, or regulatory investigations, as well as adverse publicity, 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 or EU regulations, to provide accurate information to the FDA, Competent Authorities of EEA countries or other foreign countries, 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

We have issued substantially all of our available authorized shares of common stock, and will not be able to issue additional shares for future capital raising transactions or strategic transactions unless we obtain stockholder approval to amend our restated certificate of incorporation to increase the number of authorized shares of common stock.

We have 200,000,000 authorized shares of common stock. As of February 26, 2021, we had 182,578,964 shares of common stock outstanding, 2,053,676 shares of common stock issuable upon the exercise of outstanding stock options or settlement of outstanding restricted stock units, 12,020,926 shares of common stock issuable upon the exercise of outstanding warrants, and 3,145,752 shares reserved for future issuance under our 2015 Stock Incentive Plan (the "2015 Plan"). As a result, as of such date, we had only 200,682 additional authorized shares of common stock available for issuance. We expect to seek shareholder approval at our 2021 annual meeting of shareholders to amend our restated certificate of incorporation to further increase the number of authorized shares of common stock available for issuance. Unless such amendment is approved, we will be limited in our ability to issue further shares of common stock, including in connection with potential future capital raising transactions, and we will also be limited in our ability to make new equity-based grants under the 2015 Plan beginning in 2022, or otherwise make new grants under our 2019 Sales Team Performance-Based Equity Incentive Plan. Such limitations could limit our ability to raise capital, and continue to incentivize employees.

If we fail to maintain compliance with the requirements for continued listing on the NASDAQ Capital 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 on the NASDAQ Capital Market under the symbol "CFMS." Until December 30, 2020, our common stock was listed on the NASDAQ Global Select Market which, along with the NASDAQ Capital Market, has qualitative and quantitative continued listing requirements, including corporate governance requirements, public float requirements and the \$1.00 minimum closing bid price requirement. On December 30, 2020, we transferred the listing of our common stock to the NASDAQ Capital Market because we did not meet Nasdaq's \$1.00 minimum closing bid price requirement. While we have subsequently regained compliance with this requirement, there can be no assurance that our bid price will not again fall below listing requirements. Any potential delisting of our common stock from the NASDAQ Capital 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.

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.

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

As of December 31, 2020, we had federal net operating loss, or NOL, carryforwards of \$440 million and state NOL carryforwards of \$244 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. On February 17, 2021, the Company closed an offering of our common stock off of the Shelf Registration Statement and issued and sold 80,952,381 shares of our common stock at a public offering price of \$1.05 per share, for aggregate net proceeds of approximately \$79.6 million, the Company is currently analyzing if a Section 382 ownership change occurred and if any further limitation will need to be updated in 2021.

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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal facilities consist of office space and manufacturing facilities in Billerica and Wilmington, Massachusetts, Wallingford, Connecticut, and Hyderabad, India. 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. We occupy 11,962 square feet of office space in Hyderabad, India, under a lease that expires in November 2025 with the option to extend beyond the term of the lease.

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 alleged 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's 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 infringed five patents owned by Zimmer Biomet. Zimmer Biomet alleged that our iTotol CR and iTotol PS products infringed all five asserted patents, that our iDuo product infringed 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 alleged that Zimmer Biomet's asserted patents were invalid.

On May 22, 2020, we entered into a Settlement and License Agreement with Zimmer Biomet, pursuant to which the parties agreed to terms for resolving their then-existing patent disputes. Under the Settlement and License Agreement, we and Zimmer Biomet agreed to dismiss both outstanding patent infringement lawsuits between the parties; we granted to Zimmer Biomet a royalty-free, non-exclusive, worldwide license to certain of the our patents for Zimmer Biomet's patient-specific instrumentation used with off-the-shelf knee, hip, and shoulder implants; and Zimmer Biomet granted to Conformis a fully paid-up, royalty-free, non-exclusive, worldwide license to certain Zimmer Biomet patents for our implants and patient-specific instruments for the knee. Zimmer Biomet was also required to make payments to us on specified dates through January 15, 2021, for a total amount payable of \$9.6 million, in consideration of the licenses, releases and other immunities granted by us to Zimmer Biomet. As of January 13, 2021, we had received all payments under the Settlement and License Agreement, totaling the full \$9.6 million. No payment was due from us to Zimmer Biomet.

On August 29, 2019, we filed a lawsuit against Medacta USA, Inc. in the United States District Court for the District of Delaware. We amended our complaint on December 23, 2019, and again on October 14, 2020, adding Medacta International (Medacta's USA, Inc.'s parent company) as a defendant (Medacta USA, Inc. and Medacta International SA are referred to, together, as "Medacta"). We are seeking damages for Medacta's infringement of certain of our patents related to patient-specific instrument and implant systems, alleging 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 to our original complaint, 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. Discovery in the lawsuit is ongoing.

On March 20, 2020, Osteoplastics LLC, or "Osteoplastics" filed a lawsuit against us in the United States District Court for the District of Delaware, and Osteoplastics amended its complaint on April 2, 2020. Osteoplastics alleges that our proprietary software, including our iFit software platform, and our use of our proprietary software for designing and manufacturing medical devices, including implants, infringes seven patents owned by Osteoplastics. On June 15, 2020, we filed a motion to dismiss Osteoplastics' complaint, and on October 21, 2020, the court denied the motion to dismiss. On November 2, 2020, we filed our answer to the amended complaint, denying that Conformis infringes the patents asserted by Osteoplastics. Our answer also alleges the affirmative defense that Osteoplastics' asserted patents are invalid. Discovery in the lawsuit has commenced.

On April 24, 2020, we filed a lawsuit against Wright Medical Technology, Inc. and Tornier, Inc., or "Wright Medical," in the United States District Court for the District of Delaware, and we amended our complaint on November 30, 2020. We are seeking damages for Wright Medical's infringement of certain of our patents related to patient-specific instrument and implant systems. The complaint alleges that Wright Medical's multiple lines of patient-specific shoulder instruments, as well as the implant components used in conjunction with them, infringe four of our patents. The accused product lines include Wright Medical's Tornier Blueprint™ 3D Planning + PSI shoulder replacement systems. On December 14, 2020, Wright Medical filed its answer to the amended complaint, denying that its patient-specific instrument and implant systems infringe the patents asserted by the Company. Wright Medical's answer also alleges the affirmative defense that the Company's asserted patents are invalid. Discovery in the lawsuit has commenced.

On May 8, 2020, we and an individual plaintiff filed a lawsuit against Aetna, Inc. and Aetna Life Insurance Company or "Aetna" in the United States District Court for the District of Massachusetts seeking damages for Aetna's improper denial of coverage for personalized knee implants under its health plans and the ones it administers. The complaint alleges that Aetna has violated its duties under state and federal law, including the Employee Retirement Income Security Act. On July 23, 2020, Aetna filed a motion to dismiss the complaint. The court has not yet ruled on the motion.

Adverse outcomes of these lawsuits could have a material adverse effect on our business, financial condition or results of operations. We are 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 H—Commitments and Contingencies" in this Annual Report on Form 10 -K.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

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

Certain Information Regarding the Trading of Our Common Stock

Since December 30, 2020, our common stock has traded under the symbol “CFMS” on the NASDAQ Capital Market. Prior to that date, our common stock traded on the NASDAQ Global Select Market since July 2015 under the same symbol. The following table sets forth the high and low sales price of our common stock as reported on the NASDAQ Global Market and the NASDAQ Capital Market, as applicable, for the periods indicated:

	High	Low
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
Year ended December 31, 2020:		
First Quarter	\$ 1.55	\$ 0.56
Second Quarter	\$ 1.12	\$ 0.59
Third Quarter	\$ 0.88	\$ 0.66
Fourth Quarter	\$ 0.80	\$ 0.62

Holders of Our Common Stock

As of March 1, 2021, 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 Form 10-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 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 \$19.5 billion annually and growing, and we believe our iFit technology platform is applicable to all major joints in this market. We offer a broad line of personalized knee implants and instruments designed to restore the natural shape of a patient's knee. As of December 31, 2020, we had sold a total of more than 125,000 knee implants, including more than 100,000 total knee implants and 25,000 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. We are planning for a limited commercial launch of a second stem for the Conformis Hip System in the first half of 2022. In the second half of 2021, we plan to launch a new standard knee offering, which is being designed to provide a lower-cost alternative to hospitals, outpatient surgery centers, and ASCs, while still taking full advantage of years of patient data collected through Conformis' unique business model. We are planning for a limited commercial launch of our cementless or Press Fit option for our iTotal Identity knee implant beginning during the fourth quarter of 2021 and/or first quarter of 2022, with the full commercial launch planned by the second half of 2022.

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. 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.

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.

COVID-19 Pandemic

In December 2019, a human infection originating in China was traced to a novel strain of coronavirus. The virus subsequently spread to other parts of the world, including the United States and Europe, and caused unprecedented disruptions in the global economy as efforts to contain the spread of the virus intensified. In March 2020, the World Health Organization declared this coronavirus outbreak (COVID-19) to be a pandemic. The future progression of the pandemic, including the scope, severity and duration of the pandemic, potential resurgences, the speed and effectiveness of vaccine and treatment developments, and the direct and indirect economic effects of the pandemic and containment measures, and its effects on our business and operations remain uncertain. We have experienced significantly decreased demand for our products during the pandemic as healthcare providers and individuals have de-prioritized and deferred medical procedures deemed to be elective, such as joint replacement procedures, which has had and is expected to continue to have a significant negative effect on our revenue.

Such negative effects were most pronounced during the second quarter of 2020, when a significant number of hospitals were either closed for elective procedures or otherwise operating at significantly reduced volumes. Generally, we saw an increase in procedure volumes during the summer, as many regions were able to reopen for elective procedures, with an existing patient backlog.

Within the U.S. and Germany, which are our major sales markets, estimated case counts have increased since November 2020, though cases have begun to substantially decline again in recent weeks. While elective surgery sites generally remain open and operational, we believe that the increased hospital burden has negatively impacted surgical demand and capacity, temporarily delaying many procedures. In addition, there are concerns about future strains of COVID-19. We expect that these negative effects will continue in the near-term until infection rates decline from their current level, and more of the country's population is vaccinated. However, the future progression of the pandemic remains uncertain. To the extent that individuals in these markets continue to de-prioritize or delay deferrable procedures as a result of the COVID-19 pandemic or otherwise, our business, cash flows, financial condition and results of operations could be negatively affected.

On March 20, 2020, we provided notice to our employees of a furlough of approximately 80 employees effective as of March 23, 2020 to help address decreased demand for our products. The furlough resulted in reduced production capacity at our manufacturing facilities, but sufficient to meet demand. While we have not experienced and do not currently anticipate significant interruptions in our supply chain, extended or additional quarantines, travel restrictions and other measures may significantly impact the ability of employees of our third-party suppliers to get to their places of work to manufacture the key components and materials necessary for our products. Any delay or shortage of materials or delays in delivering our products may 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. On April 17, 2020, we entered into an approximately \$4.7 million promissory note, or the PPP Note, with East West Bank under the Paycheck Protection Program, or the PPP offered by the U.S. Small Business Administration, or the SBA, to mitigate the negative financial and operational impacts of the pandemic. On April 23, 2020, we accelerated a plan to return to full-time employment the vast majority of those employees who were furloughed on March 23, 2020. This plan was completed at the end of April 2020.

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, Spain, Portugal, the Netherlands, Belgium, the Dutch Antilles, Suriname, Australia, Argentina, the United Arab Emirates, the Sultanate of Oman, Italy, San Marino, Poland 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, requiring 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.

Royalty and licensing revenue for the year ended December 31, 2020 includes revenue of \$9.6 million generated from our settlement with Zimmer Biomet for a royalty-free, non-exclusive, worldwide license to certain patents for the exploitation of patient-specific or partially patient-specific instrumentation for knee, shoulder or hip replacement and releases and other immunities. Under Accounting Standards Codification ("ASC") No. 2014-09, Revenue from Contracts with Customers ("Topic 606" or "ASC 606"), these individual rights are accounted for as a single performance obligation. The earnings process is complete and revenue is recognized upon the execution of the contract, when collectability is probable and all other revenue recognition criteria have been met. 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 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.

We provide certain information regarding our financial results or projected financial results on a non-GAAP "constant currency basis." This information estimates the impact of changes in foreign currency rates on the translation of our current or projected future period financial results as compared to the applicable comparable period. This impact is derived by taking the adjusted current or projected local currency results and translating them into U.S. Dollars based upon the foreign currency exchange rates for the applicable comparable period. It does not include any other effect of changes in foreign currency rates on our results or business. Non-GAAP information is not a substitute for, and is not superior to, information presented on a GAAP basis.

This non-GAAP financial measure may be different from non-GAAP financial measures used by other companies, limiting its usefulness for comparison purposes. Moreover, presentation of revenue on a constant currency basis is provided for year-over-year comparison purposes, and investors should be cautioned that the effect of changing foreign currency exchange rates has an actual effect on our operating results. We consider the use of a period over period revenue comparison on a constant currency basis to be helpful to investors, as it provides a revenue growth measure free of positive or negative volatility due to currency fluctuations.

Cost of revenue

We produce our computer aided designs, or CAD, in-house and in India and use them to direct most of our product manufacturing efforts. We manufacture all of our patient-specific instruments, or iJigs, tibial trays used in our total knee implants, and polyethylene tibia tray inserts for our iTotal CR and our iTotal PS product, 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. Also included in cost of revenue for the year ended December 31, 2020, are legal fees payable to external counsel in connection with our patent licensing and enforcement activities related to the Settlement and License Agreement with Zimmer Biomet.

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 and licensing revenue, to expand over time to the extent we are successful in continuing to reduce 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 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.

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, allocation of manufacturing training costs, 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.

Total other income (expenses), net

Total other income (expenses), 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, 2020 and 2019

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

Years Ended December 31,	2020		2019		2020 vs 2019	
	Amount	As a % of Total Revenue	Amount	As a % of Total Revenue	\$ Change	% Change
Revenue						
Product revenue	\$ 58,540	85 %	\$ 76,649	99 %	\$ (18,109)	(24)%
Royalty and licensing	10,221	15	780	1	9,441	1,210
Total revenue	68,761	100	77,429	100	(8,668)	(11)
Cost of revenue	35,046	51	40,692	53	(5,646)	(14)
Gross profit	33,715	49	36,737	47	(3,022)	(8)
Operating expenses:						
Sales and marketing	22,646	33	28,514	37	(5,868)	(21)
Research and development	11,939	17	12,457	16	(518)	(4)
General and administrative	24,244	35	20,895	27	3,349	16
Total operating expenses	58,829	86	61,866	80	(3,037)	(5)
Loss from operations	(25,114)	(37)	(25,129)	(32)	15	—
Total other income/(expenses), net	863	1	(3,304)	(4)	4,167	126
Loss before income taxes	(24,251)	(35)	(28,433)	(37)	4,182	15
Income tax provision	42	—	45	—	(3)	(7)
Net loss	\$ (24,293)	(35)%	\$ (28,478)	(37)%	\$ 4,185	15 %

Product revenue. Product revenue was \$58.5 million for the year ended December 31, 2020 compared to \$76.6 million for the year ended December 31, 2019, a decrease of \$18.1 million or 24%. We believe the decline is primarily due to the postponement of elective surgeries as a result of the COVID-19 pandemic.

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

Years Ended December 31,	2020		2019		2020 vs 2019	
	Amount	As a % of Product Revenue	Amount	As a % of Product Revenue	\$ Change	% Change
United States	\$ 50,736	87 %	\$ 67,151	88 %	\$ (16,415)	(24)%
Germany	6,526	11	7,598	10	(1,072)	(14)
Rest of world	1,278	2	1,900	2	(622)	(33)
Product revenue	\$ 58,540	100 %	\$ 76,649	100 %	\$ (18,109)	(24)%

Product revenue in the United States was generated through our direct sales force and independent sales representatives. Product revenue outside the United States was generated through our direct sales force and distributors. The percentage of product revenue generated in the United States was 87% for the year ended December 31, 2020 compared to 88% for the year ended December 31, 2019.

United States product revenue decreased \$16.4 million to \$50.7 million or 24% year over year. We believe the decline in revenue inside the United States was primarily due to the postponement of elective surgeries due to the COVID-19 pandemic. Germany product revenue decreased \$1.1 million to \$6.5 million, or 14% year over year.

on a reported basis and 16% on a constant currency basis. Rest of World product revenue decreased \$0.6 million to \$1.3 million, or 33% year-over-year on a reported basis and 34% on a constant currency basis, we believe primarily due to restrictions of elective surgeries in the UK related to the COVID-19 pandemic. The impact of COVID-19 is affecting all geographies.

Royalty and licensing revenue. Royalty and licensing revenue was \$10.2 million for the year ended December 31, 2020 compared to \$0.8 million for the year ended December 31, 2019, an increase of \$9.4 million or 1,210%. The increase in royalty and licensing revenue was driven by \$9.6 million in revenue recognized in the second quarter of 2020 under the Settlement and License Agreement with Zimmer Biomet.

Cost of revenue, gross profit and gross margin. Cost of revenue was \$35.0 million for the year ended December 31, 2020 compared to \$40.7 million for the year ended December 31, 2019, a decrease of \$5.6 million or 14%. The decrease was due primarily to lower volumes due to the postponement of elective surgeries we believe as a result of the COVID-19 pandemic as well as higher cancelled case expense as a percent of revenue. Gross profit was \$33.7 million for the year ended December 31, 2020 compared to \$36.7 million for the year ended December 31, 2019, a decrease of \$3.0 million or 8%. Gross margin was 49% for the year ended December 31, 2020 compared to 47% for the year ended December 31, 2019, an increase of 200 basis points. This increase in gross margin was driven primarily by the \$9.6 million licensing revenue as a result of the Settlement and License Agreement with Zimmer Biomet. Also included in cost of revenue are legal fees payable to external counsel in connection with alternative fee arrangements relating to patent licensing and enforcement activities related to the Zimmer Biomet settlement.

Sales and marketing. Sales and marketing expense was \$22.6 million for the year ended December 31, 2020 compared to \$28.5 million for the year ended December 31, 2019, a decrease of \$5.9 million or 21%. The decrease was due primarily to lower commissions of \$3.9 million, personnel costs of \$1.0 million, travel and entertainment of \$0.7 million and marketing programs of \$0.6 million. The decline in expenses were due to lower variable costs associated with the reduction in revenue and targeted expense reduction efforts to partially offset the negative impact of COVID-19. These decreases were partially offset by an increase in depreciation expense of \$0.5 million. Sales and marketing expense decreased as a percentage of total revenue to 33% for the year ended December 31, 2020 compared to 37% for the year ended December 31, 2019.

Research and development. Research and development expense was \$11.9 million for the year ended December 31, 2020 compared to \$12.5 million for the year ended December 31, 2019, a decrease of \$0.5 million or 4%. The decrease was due to allocated cost to the advance on research and development of \$1.5 million, a decrease in revenue share and clinical trial expenses of \$0.5 million, a decrease in travel and entertainment of \$0.2 million, partially offset by an increase of \$1.7 million in personnel costs. Research and development expense increased as a percentage of total revenue to 17% for the year ended December 31, 2020 from 16% for the year ended December 31, 2019.

General and administrative. General and administrative expense was \$24.2 million for the year ended December 31, 2020 compared to \$20.9 million for the year ended December 31, 2019, an increase of \$3.3 million or 16%. The increase was primarily due to higher personnel related costs of \$1.4 million, legal expense of \$1.1 million, severance expense of \$0.3 million, insurance expense of \$0.3 million, professional service expense of \$0.2 million, and taxes and fees of \$0.2 million. These increases were partially offset by decreases in outbound freight costs of \$0.1 million as a result of the lower revenue and a decrease in travel and entertainment of \$0.1 million. General and administrative expense increased as a percentage of total revenue to 35% for the years ended December 31, 2020 from 27% for the year ended December 31, 2019.

Total other income (expenses), net. Total other income (expenses), net was \$0.9 million of other income for the year ended December 31, 2020 compared to other expense of \$3.3 million for the year ended December 31, 2019, a change of \$4.2 million, or 126%. The change was primarily due to lower interest expense, net of \$0.3 million and a \$3.9 million increase in foreign currency exchange transaction income.

Income taxes. Income tax provision was \$42,000 for the year ended December 31, 2020 and \$45,000 for the year ended December 31, 2019. 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

From our inception in June 2004 through the year ended December 31, 2020, we have financed our operations primarily through private placements of preferred stock, our initial public offering in 2015, other equity financings, debt and convertible debt financings, equipment purchase loans, patent licensing, and product revenue beginning in 2007. We have not yet attained profitability and continue to incur operating losses and negative operating cash flows.

At December 31, 2020, we had an accumulated deficit of \$528.4 million.

In January 2017, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on May 9, 2017, or the 2017 Shelf Registration Statement. The 2017 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, pursuant to which we could issue and sell up to \$50 million of our common stock and entered into an Equity Distribution Agreement with Canaccord Genuity LLC (formerly Canaccord Genuity Inc.) or Canaccord, pursuant to which Canaccord agreed to sell shares of our common stock from time to time, as our agent in an "at-the-market", or ATM, offering as defined in Rule 415 promulgated under the U.S. Securities Act of 1933, as amended, or the Securities Act. We are not obligated to sell any number of shares under the Distribution Agreement. On August 4, 2020, we and Canaccord mutually agreed to terminate the Distribution Agreement, and as of that date, we had sold 2,663,000 shares under the Distribution Agreement resulting in net proceeds of \$4.4 million.

On March 23, 2020, we filed a new shelf registration statement on Form S-3 or the New Shelf Registration Statement, which was declared effective by the SEC on August 5, 2020. Under the New Shelf Registration Statement, we will be permitted 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. The New Shelf Registration Statement is intended to provide us flexibility to conduct sales of our registered securities, subject to market conditions and our future capital needs. On August 5, 2020, we filed with the SEC a prospectus supplement, for the sale and issuance of up to \$25 million of its common stock and entered into an at-the-market issuance sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, pursuant to which we may offer and sell shares of the our common stock to or through Cowen, acting as agent and/or principal, from time to time in an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including without limitation sales made by means of ordinary brokers' transactions on the NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by us. Cowen will use commercially reasonable efforts to sell the Common Stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay Cowen a commission of up to 3.0% of the gross sales proceeds of any Common Stock sold through Cowen under the Sales Agreement, and we also provided Cowen with customary indemnification rights. The shares of Common Stock being offered pursuant to the Sales Agreement will be offered and sold pursuant to the New Shelf Registration Statement. We are not obligated to make any sales of Common Stock under the Sales Agreement. The offering of shares of Common Stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all Common Stock subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms. As of December 31, 2020, we had not sold any shares under the Sales Agreement.

On December 17, 2018, we entered into a stock purchase agreement, or the "Stock Purchase Agreement," with Lincoln Park Capital, or "LPC." Upon entering into the Stock Purchase 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 over a 36-month period subject to the terms of the Stock Purchase 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 Stock Purchase 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 Stock Purchase 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 Stock Purchase 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 Stock Purchase Agreement) is below a floor price of \$0.25 per share. No warrants, derivatives, financial or business covenants are associated with the Stock Purchase 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 Stock Purchase Agreement may be terminated by us at any time, at our sole discretion, without any cost or penalty. On August 5, 2020, we filed with the SEC a prospectus supplement, for the sale and issuance of up to \$17.6 million of our common stock pursuant to the Stock Purchase Agreement dated December 17, 2018. As of December 31, 2020, we have sold 4,521,968 shares under the Stock Purchase Agreement resulting in proceeds of \$3.4 million.

On September 23, 2020, we and a healthcare-focused institutional investor entered into a subscription agreement the "Subscription Agreement", pursuant to which we sold (i) 8,512,088 shares of its common stock and accompanying warrants to purchase up to 8,512,088 shares of common stock and (ii) pre-funded warrants to purchase up to 9,492,953 shares of common stock and accompanying warrants to purchase up to 9,492,953 shares of common stock in a registered direct offering for gross proceeds of approximately \$17.3 million. The common stock (or one pre-funded warrants in lieu thereof) and accompanying warrants were sold as units, each consisting of one share (or one pre-funded warrant to purchase one share of common stock in lieu thereof) and one warrant to purchase one share of common stock, at an offering price of \$0.9581 per unit. The net proceeds to us from the offering, after deducting the placement agent's fees and other estimated offering expenses payable by us, was approximately \$15.9 million.

The pre-funded warrants became exercisable immediately upon issuance, have an exercise price of \$0.0001 per share and will be exercisable until all of the pre-funded warrants are exercised in full. As of December 31, 2020, all pre-funded warrants have been fully exercised. The warrants became exercisable immediately upon issuance, have an exercise price of \$0.8748 per share, and will expire five years from the date of issuance. As of March 3, 2021, approximately 6.0 million of these warrants have been exercised. The pre-funded warrants and the warrants each prohibit the holder from exercising any portion thereof to the extent that the holder would own more than 9.99% of the number of shares of common stock outstanding immediately after exercise. The number of shares issuable upon exercise of the warrants and pre-funded warrants and the exercise price of the warrants and pre-funded warrants is adjustable in the event of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

On June 25, 2019, we entered into a Loan and Security Agreement or the 2019 Secured Loan Agreement with Innovatus Life Sciences Lending Fund I, LP or Innovatus, as collateral agent and lender, East West Bank and the other lenders party thereto from time to time, or Lenders, pursuant to which the Lenders agreed to make term loans and to provide a revolving credit facility to us to repay existing indebtedness, for working capital and general business purposes, in a principal amount of up to \$30 million. We used the proceeds from the 2019 Secured Loan Agreement to pay off the \$15 million term loan from Oxford Finance LLC. In addition, Innovatus purchased approximately \$3 million of our common stock at the previous day's closing price. During the first quarter of 2020, we reported that we may not be able to meet our second quarter revenue covenant and would work with Innovatus with the goal of adjusting the revenue covenants under the 2019 Secured Loan Agreement. On July 1, 2020, we entered into a third amendment to the 2019 Secured Loan Agreement, which, among other things, waived the trailing six-month revenue covenant milestones that applied to the quarters ended June 30, September 30 and December 31, 2020 under the agreement, reduced the revenue covenant milestones that apply thereafter, and delays until June 25, 2021 our option to prepay all, but not less than all, of the term loans advanced under the 2019 Secured Loan Agreement. On August 20, 2020, we entered into a fourth amendment to the 2019 Secured Loan Agreement, which, among other things, waived certain provisions of the agreement that apply to Conformis India LLP. As of December 31, 2020, we were not in breach of covenants under the 2019 Secured Loan Agreement.

On March 1, 2021, we entered into a fifth amendment to the 2019 Secured Loan Agreement, which, among other things, waives the trailing six-month revenue covenant milestones that apply to the quarters ending March 31, June 30, September 30 and December 31, 2021 and reduces the revenue covenant milestones that apply in 2022. The revenue covenant milestones remain unchanged for 2023 and 2024. The amendment also increases our minimum cash covenant to \$5 million until December 31, 2021. For further information regarding the 2019 Secured Loan Agreement and the fifth amendment, see "Note I—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, 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 became eligible to receive up to an additional \$16 million in milestone payments pursuant to the License Agreement and the Development Agreement. As of December 31, 2020, we had successfully completed two of three milestones with Stryker and received \$5.0 million in the aggregate for achievement of these milestones. 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 successful completion of the milestones set forth in the Development Agreement and License Agreement.

The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted on March 27, 2020 in the United States. On April 17, 2020, we entered into an approximately \$4.7 million promissory note, or the PPP Note, with East West Bank as the lender under the PPP offered by the SBA, to mitigate the negative financial and operational impacts of the COVID-19 pandemic. The interest rate on the PPP Note is a fixed rate of 1% per annum. We are required to make one payment of all outstanding principal plus all accrued unpaid interest on April 9, 2022, or the Maturity Date. We will pay regular monthly payments in an amount equal to one month's accrued interest commencing on August 2, 2021, with all subsequent interest payments to be due on the same day of each month after that. All interest which accrues during the deferral period will be payable on the Maturity Date. According to the terms of the PPP, all or a portion of the loan as well as any accrued interest may be fully forgiven if the funds are used for payroll costs (and at least 60% of the forgiven amount must have been used for payroll), interest on certain other outstanding debt, rent, and utilities. In accordance with the CARES Act, we used the proceeds of the loan primarily for payroll costs. We submitted the loan forgiveness application to the lender on December 11, 2020. We resubmitted the application on February 23, 2021 with additional supporting documentation as requested by the lender. We're currently waiting for a final decision from the lender regarding approval of the application.

On May 22, 2020, we entered into a Settlement and License Agreement with Zimmer Biomet, Zimmer US, Inc. and Biomet Manufacturing, LLC, or collectively, Zimmer Biomet, pursuant to which the parties agreed to terms for resolving then-existing patent disputes. Under the Settlement and License Agreement, we and Zimmer Biomet agreed to dismiss both outstanding patent infringement lawsuits between the parties; we granted to Zimmer Biomet a royalty-free, non-exclusive, worldwide license to certain of our patents for Zimmer Biomet's patient-specific instrumentation used with off-the-shelf knee, hip, and shoulder implants; and Zimmer Biomet granted us a fully paid-up, royalty-free, non-exclusive, worldwide license to certain Zimmer Biomet patents for our implants and patient-specific instruments for the knee. Under the agreement, Zimmer Biomet was required to pay us a total of \$9.6 million in installments through January 15, 2021, and all such payments were made and received by such date. No payment was due from us to Zimmer Biomet.

On February 17, 2021, we closed an offering of our common stock off of the Shelf Registration Statement and issued and sold 80,952,381 shares of our common stock at a public offering price of \$1.05 per share, for aggregate net proceeds of approximately \$79.6 million. For further information regarding this public offering, see "Note O—Subsequent Events - 2021 Common Stock Offering" in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

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 sales of our products, including the successful full commercial launch of the Conformis Hip System, successful completion of the milestones set forth in the Development Agreement and License Agreement, potential payments from Stryker

pursuant to the Distribution Agreement, funds from the February 17, 2021 common stock offering, available sales of shares under the Sales Agreement and the Stock Purchase Agreement, and revenues that we may generate in connection with licensing our intellectual property. Additionally, in order for us to meet our long-term operating plan, revenue growth, gross margin improvements and leveraging operating expenses will be necessary to reduce cash used in operations. We will need to generate significant additional revenue to achieve and maintain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. It is also possible that we may allocate significant amounts of capital toward products or technologies for which market demand is lower than anticipated and, as a result, abandon such efforts. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, or if we expend capital on projects that are not successful, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, and we may even have to scale back our operations. Our failure to become and remain profitable could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue to fund our operations.

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

At December 31, 2020, we had cash and cash equivalents of \$28.7 million and \$0.5 million in restricted cash allocated to lease deposits. Based on our current operating plan, we expect to fund our operations, capital expenditure requirements and debt service with existing cash and cash equivalents as of December 31, 2020, funds from the February 17, 2021 common stock offering, anticipated revenue from operations, the successful completion of the milestones set forth in the Development Agreement and License Agreement, revenue that may be generated in connection with licensing intellectual property, available sales of shares under the Sales Agreement and the Stock Purchase Agreement and funds from potential exercises of our common stock warrants. We have based this expectation on assumptions that may prove to be wrong, such as the revenue that we expect to generate from the sale of our products, the gross profit we expect to generate from those revenues, and the fact that we could use our capital resources sooner than we expect.

The COVID-19 pandemic has negatively impacted and will continue to impact our business, operations and financial condition. As part of our response to COVID-19, we took certain measures in preserving liquidity. In addition to the furlough implemented in March 2020, we have eliminated, reduced, or are deferring significant non-essential expense including sales, marketing, quality, clinical, regulatory and general and administrative expense. Non-essential programs have been eliminated or deferred where possible. In addition, we are working with suppliers to help match future revenue and expense.

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,			
	2020	2019	\$ Change	% Change
Net cash (used in) provided by:				
Operating activities	\$ (18,310)	\$ (2,838)	\$ (15,472)	(545)%
Investing activities	(3,249)	4,324	(7,573)	(175)
Financing activities	23,757	8,527	15,230	179
Effect of exchange rate on cash	81	1	80	8,000
Total	\$ 2,279	\$ 10,014	\$ (7,735)	(77)%

Net cash used in operating activities. Net cash used in operating activities was \$18.3 million for the year ended December 31, 2020 and \$2.8 million for the year ended December 31, 2019, an increase of \$15.5 million. These amounts primarily reflect net losses of \$24.3 million for the year ended December 31, 2020 and \$28.5 million for the year ended December 31, 2019. The increase in net cash used in operating activities for the year ended December 31, 2020 was affected by a decrease in accounts payable, accrued expenses and other liabilities of \$4.8 million, a decrease in contract liability of \$10.0 million and advances for research and development of \$4.5

million under the Asset Purchase Agreement with Stryker, a decrease in inventory of \$2.0 million, and a decrease in prepaid and other assets of \$2.1 million, partially offset by an increase in royalty and licensing receivable of \$1.1 million. Non-cash reconciling items include an increase in unrealized foreign exchange income/loss of \$3.8 million, partially offset by a decrease from loss from debt extinguishment of \$1.1 million.

Net cash (used in) provided by investing activities. Net cash used in investing activities was \$3.2 million for the year ended December 31, 2020 compared to \$4.3 million cash provided by investing activities for the year ended December 31, 2019, a decrease of \$7.6 million. These amounts primarily reflect a decrease in cash provided from matured investments of \$7.3 million, and an increase in cost related to the acquisition of property and equipment of \$0.3 million.

Net cash provided by financing activities. Net cash provided by financing activities was \$23.8 million for the year ended December 31, 2020 and \$8.5 million for the year ended December 31, 2019, an increase of \$15.2 million. The increase is due to \$15.9 million of proceeds from the issuance of common stock and prefunded warrants under the registered direct offering, \$4.7 million of proceeds from the issuance of the PPP loan and net proceeds of \$3.1 million from issuance of common stock, compared to the net proceeds of \$3.3 million from the refinancing of the Oxford debt, and net proceeds of \$5.0 million from issuance of common stock for the year ended December 31, 2019.

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.

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, ranges, depending on the particular product, from 2.5% to 5.6%. We incurred aggregate revenue share expense, included in research and development, including all amounts payable under our scientific advisory board revenue share agreements of \$1.6 million during the year ended December 31, 2020, and representing 2.7% of product revenue, \$2.0 million during the year ended December 31, 2019, representing 2.6% of product revenue. For further information, see “Note H—Commitments and Contingencies—Revenue Share Agreements” 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, 2020, 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 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. We believe the critical accounting policies and estimates that require the use

of significant estimates and judgments in the preparation of our consolidated financial statements include revenue recognition, inventory valuations, impairment assessments, and income tax reserves and related allowances. 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 and estimates 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, Spain, Portugal, the Netherlands, Belgium, the Dutch Antilles, Suriname, Australia, Argentina, the United Arab Emirates, the Sultanate of Oman, Italy, San Marino, Poland 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. 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, 2020. 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.

Royalty and licensing revenue for the year ended December 31, 2020 includes revenue of \$9.6 million generated from our settlement with Zimmer Biomet for a royalty-free, non-exclusive, worldwide license to certain patents for the exploitation of patient-specific or partially patient-specific instrumentation for knee, shoulder or hip replacement and releases and other immunities. Under ASC 606, these individual rights are accounted for as a single performance obligation. The earnings process is complete and revenue is recognized upon the execution of the contract, when collectability is probable and all other revenue recognition criteria have been met. Ongoing royalty revenue is generated from our agreement with MicroPort Orthopedics Inc., a wholly owned subsidiary of MicroPort Scientific Corporation, or collectively, MicroPort. Under ASC 606, the license agreement with MicroPort indicates that the licenses are functional and thus revenue recognition is upon the license execution date.

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 became eligible to receive up to an additional \$16 million in milestone payments pursuant to the License Agreement and the Development Agreement. As of December 31, 2020, we had successfully completed two of three milestones with Stryker and received \$5.0 million in the aggregate for achievement of these milestones and advances for research and development. 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 successful completion of the milestones set forth in the Development Agreement and License Agreement.

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, 2020 we had \$14.0 million recognized as a short-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.

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, 2020, and 2019, we recognized provisions of \$2.7 million, and \$2.8 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.

Long-lived assets

We test impairment of long-lived assets when events or changes in circumstances indicate that the assets might be impaired. The asset group is tested for recoverability by comparing the net carrying value of the asset group to the undiscounted net cash flows to be generated from the use and eventual disposition of that asset group.

During the quarters ended March 31, 2020, June 30, 2020, September 30, 2020 and December 31, 2020, there were changes in circumstances that led us to believe that our long-lived assets may be impaired. We had experienced a significant decrease in demand for our products we believe as a result of the COVID-19 pandemic, and as such, an assessment for recoverability was performed. We evaluated whether the estimated undiscounted cash flows, including estimated terminal value, generated from the asset group were sufficient to support the carrying value of the assets. If the carrying amount of the asset group is not recoverable, an impairment loss is recognized if the carrying amount exceeds the fair value. During the year ended December 31, 2020, no such impairment charges were recognized. During the year ended December 31, 2019, we identified long-lived assets that have become impaired and recorded \$0.1 million in impairment charges. Impairment charges are included in General and administrative expense.

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, we consider 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, we rely upon assumptions and estimates of future activity including the reversal of temporary differences. Presently, we believe 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. We review our tax positions on an annual basis and more frequently as facts surrounding tax positions change. Based on these future events, we may recognize uncertain tax positions or reverse current uncertain tax positions, the impact of which would affect the consolidated financial statements.

We have operations in Germany, the United Kingdom, and since November 6, 2020, India. The operating results of these operations will be permanently reinvested in those jurisdictions. As a result, we have only provided for income taxes at local rates when required. In April 2020, new interpretations of a German law related to intellectual property and withholding tax were released. We are currently evaluating whether the interpretations will have an impact on our consolidated financial statements.

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 we can recognize them and therefore, we have accounted for a cumulative-effect adjustment of \$7.7 million during the year ended December 31, 2019 to record excess tax benefits. Since we have a full valuation allowance on all deferred taxes, this has no impact on retained earnings or our tax position.

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") which included modifications to the limitation on business interest expense, net operating loss provisions, and other various U.S. tax law updates. We do not expect that these aspects of the CARES Act will have a material impact on our consolidated financial statements.

On December 27, 2020, the U.S. government enacted the Consolidated Appropriations Act, 2021 "the Act", which included various tax extenders, an update to meals and entertainment expensing, and the deductibility of expenses related to PPP loan proceeds. We applied the Act in regards to expenses related to the PPP loan proceeds, which previously would have been non-deductible.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Conformis, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Conformis, Inc. (a Delaware corporation) and subsidiaries (the “Company”) as of December 31, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, 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 regarding 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.

Critical audit matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of long-lived assets

As described further in Note B to the consolidated financial statements, the Company evaluates long-lived assets for impairment when events or changes in circumstances exist that may indicate that the carrying amount of the asset group is no longer recoverable. The Company identified triggering events for impairment in each of the three months ended March 31, 2020, June 30, 2020, September 30, 2020, and December 31, 2020. Accordingly, we identified the valuation of long-lived assets as a critical audit matter.

The principal considerations for our determination of the valuation of long-lived assets as a critical audit matter is due to significant judgments and estimates made by management when determining whether an asset group may be impaired. Significant judgments and estimates included forecasted cash flows and terminal value. This required a high degree of auditor judgment and an increased extent of effort when evaluating the reasonableness of management's judgments and estimates.

Our audit procedures related to the Company's test for impairment of long-lived assets included the following, among others:

- We tested management's ability to forecast by comparing actual results to prior forecasts.
- We tested the reasonableness of management's forecasted cash flows by considering both positive and negative evidence impacting the forecasts in comparison to market and industry factors and trends, and historical trends. Additionally, we performed analysis to test the sensitivity of management's forecasts.
- We evaluated management's determination of the asset group and identification of the primary asset.
- With the assistance of our valuation specialists, we evaluated the appropriateness of management's valuation methodologies and the reasonableness of key assumptions by developing a range of independent estimates for a terminal value using market participant revenue multiples and comparing to the terminal value selected by management.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2008.

Boston, Massachusetts
March 3, 2021

CONFORMIS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2020	December 31, 2019
Assets		
Current Assets		
Cash and cash equivalents	\$ 28,673	\$ 26,394
Accounts receivable, net	8,515	11,066
Royalty and licensing receivable	1,256	165
Inventories	12,585	12,074
Prepaid expenses and other current assets	2,315	2,815
Total current assets	53,344	52,514
Property and equipment, net	12,240	13,356
Operating right-of-use assets	5,215	5,853
Other Assets		
Restricted cash	462	462
Other long-term assets	239	211
Total assets	\$ 71,500	\$ 72,396
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 4,918	\$ 6,920
Accrued expenses	7,213	7,135
Operating lease liabilities	1,620	1,469
Advance on research and development	3,168	2,331
Contract liability	14,000	—
Total current liabilities	30,919	17,855
Other long-term liabilities	—	1,500
Contract liability	—	12,000
Long-term debt, less debt issuance costs	25,003	19,623
Operating lease liabilities	4,206	5,071
Total liabilities	60,128	56,049
Commitments and contingencies (Note H)		
Stockholders' equity		
Preferred stock, \$0.00001 par value:		
Authorized: 5,000,000 shares authorized at December 31, 2020 and December 31, 2019; no shares issued and outstanding as of December 31, 2020 and December 31, 2019	—	—
Common stock, \$0.00001 par value:		
Authorized: 200,000,000 shares authorized at December 31, 2020 and December 31, 2019; 95,546,577 and 70,427,400 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	543,809	521,356
Accumulated deficit	(528,438)	(504,145)
Accumulated other comprehensive loss	(4,000)	(865)
Total stockholders' equity	11,372	16,347
Total liabilities and stockholders' equity	\$ 71,500	\$ 72,396

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,	
	2020	2019
Revenue		
Product	\$ 58,540	\$ 76,649
Royalty and licensing	10,221	780
Total revenue	68,761	77,429
Cost of revenue	35,046	40,692
Gross profit	33,715	36,737
Operating expenses		
Sales and marketing	22,646	28,514
Research and development	11,939	12,457
General and administrative	24,244	20,895
Total operating expenses	58,829	61,866
Loss from operations	(25,114)	(25,129)
Other income and expenses		
Interest income	76	330
Interest expense	(2,373)	(2,942)
Foreign currency exchange transaction income (loss)	3,160	(692)
Total other income (expenses)	863	(3,304)
Loss before income taxes	(24,251)	(28,433)
Income tax provision	42	45
Net loss	\$ (24,293)	\$ (28,478)
Net loss per share - basic and diluted	\$ (0.34)	\$ (0.44)
Weighted average common shares outstanding - basic and diluted	71,699,615	64,122,455

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,	
	2020	2019
Net loss	\$ (24,293)	\$ (28,478)
Other comprehensive (loss) income		
Foreign currency translation adjustments	(3,135)	605
Comprehensive loss	<u>\$ (27,428)</u>	<u>\$ (27,873)</u>

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, 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
Issuance of common stock—restricted stock	3,721,205	—	2	—	—	2
Issuance of common stock—LPC offering	2,600,000	—	2,403	—	—	2,403
Issuance of common stock—ATM offering	792,931	—	746	—	—	746
Issuance of common stock and pre-funded warrants under registered direct offering, less issuance costs of \$1.4 million	8,512,088	—	15,895	—	—	15,895
Issuance of common stock upon exercise of pre-funded warrants	9,492,953	—	1	—	—	1
Compensation expense related to issued stock options and restricted stock awards	—	—	3,406	—	—	3,406
Net loss	—	—	—	(24,293)	—	(24,293)
Other comprehensive loss	—	—	—	—	(3,135)	(3,135)
Balance, December 31, 2020	95,546,577	\$ 1	\$ 543,809	\$ (528,438)	\$ (4,000)	\$ 11,372

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,	
	2020	2019
Cash flows from operating activities		
Net loss	\$ (24,293)	\$ (28,478)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	4,366	4,237
Stock-based compensation expense	3,406	2,837
Unrealized foreign exchange (income) loss	(3,214)	606
Non-cash lease expense	1,180	1,146
Provision for bad debts on trade receivables	50	106
Impairment of long-term assets	—	69
Disposal of long-term assets	—	(200)
Loss on extinguishment of debt	—	1,085
Non-cash interest expense	712	423
Accretion on investments	—	(4)
Changes in operating assets and liabilities:		
Accounts receivable	2,501	2,070
Royalty and licensing receivable	(1,091)	(20)
Inventories	(512)	(2,539)
Prepaid expenses and other assets	430	(1,623)
Accounts payable, accrued expenses, and other liabilities	(3,182)	1,615
Contract liability	2,000	12,000
Advance on research and development	(663)	3,832
Net cash used in operating activities	(18,310)	(2,838)
Cash flows from investing activities:		
Acquisition of property and equipment	(3,249)	(2,926)
Maturity of investments	—	7,250
Net cash (used in) provided by investing activities	(3,249)	4,324
Cash flows from financing activities:		
Proceeds from exercise of common stock options	—	184
Proceeds from exercise of pre-funded warrants	1	—
Debt issuance costs	(10)	(737)
Loss on extinguishment of debt	—	(919)
Proceeds from issuance of debt	4,720	20,000
Payments on long-term debt	—	(15,000)
Net proceeds from issuance of common stock	3,151	4,999
Issuance of common stock and pre-funded warrants under registered direct offering, net	15,895	—
Net cash provided by financing activities	23,757	8,527
Foreign exchange effect on cash and cash equivalents	81	1
Increase in cash, cash equivalents, and restricted cash	2,279	10,014
Cash, cash equivalents, and restricted cash beginning of period	26,856	16,842
Cash, cash equivalents, and restricted cash end of period	\$ 29,135	\$ 26,856
Supplemental information:		
Cash paid for interest	1,413	2,123
Non-cash investing and financing activities		
Operating leases right-of-use assets obtained in exchange for lease obligations	543	6,988

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

CONFORMIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note A—Organization and Basis of Presentation

Conformis, Inc. (together with its subsidiaries, collectively, 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, individualized, or sometimes as customized, to fit and conform to each patient's unique anatomy. The Company offers a broad line of sterile, personalized knee and hip implants and single-use instruments delivered to hospitals. The Company's proprietary iFit technology platform is potentially applicable to all major joints.

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 June 2004, it has financed its operations primarily through private placements of preferred stock, its initial public offering in July 2015, other equity financings, debt and convertible debt financings, equipment purchase loans, patent licensing, and product revenue beginning in 2007. The Company has not yet attained profitability and continues to incur operating losses and negative operating cash flows. At December 31, 2020, the Company had an accumulated deficit of \$528.4 million and cash and cash equivalents of \$28.7 million, and \$0.5 million in restricted cash allocated to a lease deposit.

The Company expects that its existing cash and cash equivalents as of December 31, 2020, funds from the February 17, 2021 common stock offering, funds from potential exercises of its common stock warrants, anticipated revenue from operations, and the successful completion of the milestones set forth in the Development Agreement and License Agreement will enable the Company to fund its operations, capital expenditure requirements and debt service for at least the next 12 months from the date of filing. In order for the Company to meet its long-term operating plan, revenue growth, margin improvements and leveraging operating expenses will be necessary to reduce cash used in operations, and the Company will need to successfully complete the remaining milestone set forth in the Development Agreement and the License Agreement which cannot be assured.

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. For further information regarding the 2019 Secured Loan Agreement and the Amendments, see "Note I—Debt and Notes Payable" in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

On February 17, 2021, the Company closed an offering of its common stock off of the Shelf Registration Statement and issued and sold 80,952,381 shares of its common stock at a public offering price of \$1.05 per share, for aggregate net proceeds of approximately \$79.6 million. For further information regarding this public offering, see "Note O—Subsequent Events - 2021 Common Stock Offering" in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

In December 2019, a human infection originating in China was traced to a novel strain of coronavirus. The virus subsequently spread to other parts of the world, including the United States and Europe, and caused unprecedented disruptions in the global economy as efforts to contain the spread of the virus intensified. In March 2020, the World Health Organization declared this coronavirus outbreak (COVID-19) to be a pandemic. The future progression of the pandemic, including the scope, severity and duration of the pandemic, potential resurgences, the speed and effectiveness of vaccine and treatment developments, and the direct and indirect economic effects of the pandemic and containment measures, and its effects on the Company's business and operations remain highly

uncertain. The Company has experienced significantly decreased demand for its products during the pandemic as healthcare providers and individuals have de-prioritized and deferred medical procedures deemed to be elective, such as joint replacement procedures, which has had and is expected to continue to have a significant negative effect on the Company's revenue. Such negative effects were most pronounced during the second quarter of 2020, when a significant number of hospitals were either closed for elective procedures or otherwise operating at significantly reduced volumes. Generally, the Company saw an increase in procedure volumes during the summer, as many regions were able to reopen for elective procedures, with an existing patient backlog.

Within the U.S. and Germany, which are the Company's major sales markets, estimated case counts have increased since November 2020. In particular, case counts and hospitalizations have increased substantially in many parts of the U.S. over the last three months, and hospitals continue to face capacity constraints. While elective surgery sites generally remain open and operational, the Company believes that the increased hospital burden has negatively impacted surgical demand and capacity, temporarily delaying many procedures. In addition, there are concerns about future strains of COVID-19. The Company expects that these negative effects will continue in the near-term until infection rates decline from their current level, and more of the country's population is vaccinated. However, the future progression of the pandemic remains uncertain. To the extent that individuals in these markets continue to de-prioritize or delay deferrable procedures as a result of the COVID-19 pandemic or otherwise, our business, cash flows, financial condition and results of operations could be negatively affected.

Basis of presentation and use of estimates

The preparation of consolidated financial statements in conformity with generally accepted accounting principles in the United States ("U.S. GAAP") 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, impairment assessments, income tax reserves and related allowances, and the lives of property and equipment. Actual results may differ from those estimates.

Note B—Summary of Significant Accounting Policies

Concentrations of credit risk and other risks and uncertainties

Financial instruments that subject the Company to credit risk primarily consist of cash, cash equivalents and accounts receivable. The Company maintains the majority of its cash with accredited financial institutions. The associated risk of concentration is mitigated by banking with credit worthy financial institutions. The Company had \$1.0 million as of December 31, 2020 and \$0.8 million as of December 31, 2019 held in foreign bank accounts, that were not federally insured.

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 year ended December 31, 2020, Zimmer Biomet represented 14% of total revenue. For the year ended December 31, 2019, no customer represented greater than 10% of revenue. As of December 31, 2020, payments due from Zimmer Biomet represented 13% of our total net receivable balance. As of December 31, 2019, there were no customers that represented greater than 10% of total net receivable balance.

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, ConforMIS India LLP; and ConforMIS Cares LLC. All intercompany balances and transactions have been eliminated in consolidation.

Cash, cash equivalents and restricted cash

The Company considers all highly liquid investment instruments with original maturities of 90 days or less when purchased, to be cash equivalents. The Company's cash equivalents consist of demand deposits and money

market accounts, in addition to cash deposits in excess of federally insured limits. Demand deposits and money market accounts are carried at cost which approximates their fair value. The Company has recorded restricted cash of \$0.5 million as of December 31, 2020 and 2019. 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, 2020	December 31, 2019
Cash and cash equivalents	\$ 28,673	\$ 26,394
Restricted cash	462	462
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	<u>\$ 29,135</u>	<u>\$ 26,856</u>

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 Accounting Standards Codification ("ASC") No. 2014-09, Revenue from Contracts with Customers ("Topic 606" or "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, the 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, 2020 and 2019, the Company recognized provisions of \$2.7 million and \$2.8 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.

Long-lived assets

The Company tests impairment of long-lived assets when events or changes in circumstances indicate that the assets might be impaired. The asset group is tested for recoverability by comparing the net carrying value of the asset group to the undiscounted net cash flows to be generated from the use and eventual disposition of that asset group. During the quarters ended March 31, 2020, June 30, 2020, September 30, 2020 and December 31, 2020, there were changes in circumstances that led the Company to believe that its long-lived assets may be impaired. The Company had experienced a significant decrease in demand for its products the Company believes as a result of the COVID-19 pandemic, and as such, an assessment for recoverability was performed. The Company evaluated whether the estimated undiscounted cash flows, including estimated terminal value, generated from the asset group were sufficient to support the carrying value of the assets. If the carrying amount of the asset group is not recoverable, an impairment loss is recognized if the carrying amount exceeds the fair value. During the year ended December 31, 2020, no such impairment charges were recognized. During the year ended December 31, 2019, the Company identified long-lived assets that have become impaired and recorded \$0.1 million in impairment charges. Impairment charges are included in General and administrative expense.

Leases

The Company adopted Accounting Standards Update ("ASU") No. 2016-02-Leases ("Topic 842" or "ASC 842"), as of January 1, 2019, in accordance with ASU No. 2018-11-Leases ("Topic 842" or "ASU 2018-11"), issued by the Financial Accounting Standards Board (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 and are not expected to be renewed for a total term of more than 12 months; 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 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 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 operating lease right-of-use assets are subsequently assessed for impairment in accordance with the Company's accounting policy for long-lived assets. The adoption of the standard did not impact the Company's consolidated net earnings and had no impact on cash flows.

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, 2020. 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, 2020 and 2019, the Company did not have contract assets or liabilities recorded on the Consolidated Balance Sheets derived from product revenue.

Royalty and Licensing Revenue Recognition

The Company receives ongoing sales-based royalties under its agreement with MicroPort Orthopedics Inc., a wholly owned subsidiary of MicroPort Scientific Corporation. 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.

As of December 31, 2020, the Company had completed two of three milestones set forth in the License Agreement and the Development Agreement and received \$5.0 million in the aggregate for achievement of these milestones. Under the long-term Distribution Agreement, the Company will supply patient specific instrumentation to Stryker. The Stryker Agreements contain termination provisions pursuant to which, under certain circumstances, Stryker may be able to terminate the Development Agreement and oblige the Company to repay a portion of the initial payment. In other 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 paying the Company 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, 2020, the Company recorded \$14.0 million as a short-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 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 termination by Stryker and Stryker's election to purchase the license rights.

On May 22, 2020 the Company entered into a Settlement and License Agreement with Zimmer Biomet, pursuant to which both parties have agreed to terms for resolving all of their existing patent disputes. In consideration of the licenses, releases, covenants and other immunities granted by the Company to Zimmer Biomet, Zimmer Biomet was required to pay the Company \$3.5 million promptly after execution of the Settlement and License Agreement, which it has, and additional payments on specified dates through January 15, 2021, for a total amount payable of \$9.6 million. The agreement provides for the grant of the licenses, covenants-not-to-sue, releases, and other significant deliverables upon execution of the contract. These individual rights are not accounted for as separate performance obligations as (i) the nature of the promise, within the context of the agreement, is to transfer combined items to which the promised rights are inputs and (ii) the Company's promise to transfer each individual right described above to Zimmer Biomet is not separately identifiable from other promises in the agreement. As a result, the Company accounts for the promises in the agreement as a single performance obligation. Zimmer Biomet legally obtained control of the license and other rights upon execution of the contract. As such, the earnings process is complete and revenue was recognized upon the execution of the contract, when collectability became probable and all other revenue recognition criteria had been met within the scope of ASC 606. In connection with the Settlement and License Agreement, the Company recognized revenue of \$9.6 million during the year ended December 31, 2020. See "Note H—Commitments and Contingencies, Legal proceedings" for further discussion of the Zimmer Biomet settlement.

Disaggregation of Revenue

See "Note L—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, 2020 and 2019 (in thousands):

	Years Ended December 31,	
	2020	2019
Beginning Balance	\$ 127	\$ 96
Provision related to current period sales	146	145
Adjustment related to prior period sales	(55)	20
Payments or credits issued to customer	(137)	(134)
Ending Balance	\$ 81	\$ 127

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 under ASC 606.

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 \$1.7 million and \$1.8 million for the years ended December 31, 2020 and 2019, 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) approval of the developed product. As of December 31, 2020, the Company met the two of three milestones under the Development Agreement.

The Company recognized \$1.7 million and \$0.2 million in Research and development expense for the years ended December 31, 2020 and 2019 respectively, which was offset by a portion of the advance on research and development received upon execution of the agreements and additional payments received for the achievement of milestones 1 and 2. As of December 31, 2020, the remaining portion of the advance on research and development of \$3.2 million is classified as a short-term liability within Advance on research and development on the Consolidated Balance Sheets and will be used to offset future expenses incurred under the Development Agreement.

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 for each of the years ended December 31, 2020 and 2019.

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 L—Segment and Geographic Data."

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 quarter. Net translation gains and losses are recorded in Accumulated other comprehensive (loss) income. Gains and losses from foreign currency 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, the United Kingdom, and since November 6, 2020, India. 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. In April 2020, new interpretations of a German law related to intellectual property and withholding tax were released. The Company is currently evaluating whether the interpretations will have an impact on its consolidated financial statements.

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 March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") which included modifications to the limitation on business interest expense, net operating loss provisions, and other various U.S. tax law updates. The Company does not expect that these aspects of the CARES Act will have a material impact on its consolidated financial statements.

On December 27, 2020, the U.S. government enacted the Consolidated Appropriations Act, 2021 "the Act", which included various tax extenders, an update to meals and entertainment expensing, and the deductibility of expenses related to the Paycheck Protection Program ("PPP") loan proceeds. The Company applied the Act in regards to expenses related to the PPP loan proceeds, which previously would have been non-deductible.

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):

(in thousands, except share and per share data)	Years Ended December 31,	
	2020	2019
Numerator:		
Numerator for basic and diluted loss per share:		
Net loss	\$ (24,293)	\$ (28,478)
Denominator:		
Denominator for basic loss per share:		
Weighted average shares	71,699,615	64,122,455
Basic loss per share attributable to Conformis, Inc. stockholders	\$ (0.34)	\$ (0.44)
Diluted loss per share attributable to Conformis, Inc. stockholders	\$ (0.34)	\$ (0.44)

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,	
	2020	2019
Stock options, restricted stock awards, performance awards	970,257	2,992,120
Total	970,257	2,992,120

Note C—Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Total receivables	\$ 8,805	\$ 11,401
Allowance for doubtful accounts and returns	(290)	(335)
Accounts receivable, net	\$ 8,515	\$ 11,066

The beginning accounts receivable balance as of January 1, 2020 and 2019, was \$11.1 million and \$13.2 million, respectively. All activity within accounts receivables relate to normal operational activity from the period. Accounts receivable included unbilled receivable of \$1.0 million and \$2.1 million for the years ended December 31, 2020 and 2019. Write-offs related to accounts receivable were approximately \$75,000 and \$187,000, for the years ended December 31, 2020 and 2019, respectively.

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

	December 31, 2020	December 31, 2019
Beginning balance	\$ (335)	\$ (390)
Provision for bad debts on trade receivables	(50)	(106)
Other allowances	20	(26)
Accounts receivable write-offs	75	187
Ending balance	\$ (290)	\$ (335)

Note D—Inventories

Inventories consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Raw Material	\$ 5,513	\$ 6,171
Work in process	1,833	1,717
Finished goods	5,239	4,186
Total Inventories	<u>\$ 12,585</u>	<u>\$ 12,074</u>

Note E—Property and Equipment

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

	Estimated Useful Life (Years)	December 31, 2020	December 31, 2019
Equipment	5-7	\$ 19,461	\$ 19,011
Furniture and fixtures	5-7	864	864
Computer and software	3	9,873	9,561
Leasehold improvements	3-7	2,068	2,008
Reusable instruments	5	5,739	3,402
Molding and Tooling	5	91	—
Total property and equipment		38,096	34,846
Accumulated depreciation		(25,856)	(21,490)
Property and equipment, net		<u>\$ 12,240</u>	<u>\$ 13,356</u>

Depreciation expense related to property and equipment was \$4.4 million and \$4.1 million for the years ended December 31, 2020 and 2019, respectively. During the year ended December 31, 2020, the Company did not recognize an impairment charge. In 2019 the Company identified long-lived assets that have become impaired and recorded \$0.1 million in impairment charges.

Note F—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Accrued employee compensation	\$ 3,365	\$ 3,198
Accrued legal expense	952	310
Accrued consulting expense	21	21
Accrued vendor charges	766	1,037
Accrued revenue share expense	697	1,050
Accrued clinical trial expense	306	394
Accrued other	1,106	1,125
	<u>\$ 7,213</u>	<u>\$ 7,135</u>

Note G—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 design and manufacturing facilities in leased buildings located in Wilmington, Massachusetts Wallingford, Connecticut and Hyderabad, India.

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, 2020, 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 were \$1.6 million for the years ended December 31, 2020 and 2019, respectively. The components of lease expense and related cash flows were as follows (in thousands):

	<u>December 31, 2020</u>	<u>December 31, 2019</u>
Rent expense	\$ 1,536	\$ 1,526
Variable lease cost ⁽¹⁾	350	378
	<u>\$ 1,886</u>	<u>\$ 1,904</u>

(1) Variable operating lease expenses consist primarily common area maintenance and real estate taxes for the years ended December 31, 2020 and 2019.

As of December 31, 2020, the remaining weighted-average lease term of the operating leases was 4.26 years and the weighted-average discount rate was 6.0%.

The future minimum rental payments under these agreements as of December 31, 2020 were as follows (in thousands):

<u>Year</u>	<u>Minimum Lease Payments</u>
2021	1,735
2022	1,527
2023	1,187
2024	1,217
2025	946
Total lease payments	<u>\$ 6,612</u>
Present value adjustment	(786)
Present value of lease liabilities	<u>\$ 5,826</u>

Note H—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.

The Company incurred aggregate revenue share expense including all amounts payable under the Company's scientific advisory board revenue share agreements of \$1.6 million during the year ended December 31, 2020, representing 2.7% of product revenue and \$2.0 million during the year ended December 31, 2019, representing 2.6% of product revenue. Revenue share expense is included in research and development.

Other obligations

In the ordinary course of business, the Company is a party to certain non-cancellable contractual obligations typically related to product royalty. 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, 2020 (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⁾	\$ 1,108	\$ 179	\$ 329	\$ 300	\$ 300

(1) Represents amounts payable under our product royalty agreement and operating leases for office equipment.

(2) This table does not include: (a) revenue share obligations to past and present members of our scientific advisory board, 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 "Note H—Revenue share agreements" for a description of our revenue share arrangements.

There have been no contingent liabilities requiring accrual at December 31, 2020 or December 31, 2019.

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., 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 alleged that Zimmer Biomet's multiple lines of patient-specific instruments, as well as the implant components used in conjunction with them, infringe four of the Company's patents. The accused product lines included Zimmer Biomet's 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 the Company infringed five patents owned by Zimmer Biomet. Zimmer Biomet alleged that the Company's iTot CR and iTot PS products infringed all five asserted patents, that the Company's iDuo product infringed three of the asserted patents, and that the Company's iUni product infringed two of the asserted patents. On January 13, 2020, Zimmer Biomet filed a motion to dismiss the Company's complaint, and the Company filed its answer to Zimmer Biomet's complaint, denying that the Company's products infringed Zimmer Biomet's asserted patents. The Company's answer also alleged that Zimmer Biomet's asserted patents were invalid.

On May 22, 2020, the Company entered into a Settlement and License Agreement, with Zimmer Biomet, Zimmer US, Inc. and Biomet Manufacturing, LLC, or collectively, Zimmer Biomet, pursuant to which the parties agreed to terms for resolving then existing patent disputes. Under the Settlement and License Agreement, the Company and Zimmer Biomet agreed to dismiss both outstanding patent infringement lawsuits between the parties,

the Company granted to Zimmer Biomet a royalty-free, non-exclusive, worldwide license to certain of the Company's patents for Zimmer Biomet's patient-specific instrumentation used with off-the-shelf knee, hip, and shoulder implants, and Zimmer Biomet granted to the Company a fully paid-up, royalty-free, non-exclusive, worldwide license to certain Zimmer Biomet patents for the Company's implants and patient-specific instruments for the knee. Under the agreement, Zimmer Biomet was required to pay the Company a total of \$9.6 million in installments through January 15, 2021, and all such payments were made and received by such date. No payment was due from the Company to Zimmer Biomet under the agreement.

On August 29, 2019, the Company filed a lawsuit against Medacta USA, Inc. in the United States District Court for the District of Delaware. The Company amended its complaint on December 23, 2019, and again on October 14, 2020, adding Medacta International SA (Medacta USA, Inc.'s parent company) as a defendant (Medacta USA, Inc. and Medacta International SA are referred to, together, as "Medacta"). The Company is seeking damages for Medacta's infringement of certain of the Company's patents related to patient-specific instrument and implant systems, alleging that Medacta's multiple lines of patient-specific instruments, as well as the implant components used in conjunction with them, infringe four of the Company's 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 to the Company's original complaint, 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 the Company's asserted patents are invalid. The Company expects that Medacta will similarly respond to our amended complaint. Discovery in the lawsuit has commenced and is ongoing.

On March 20, 2020, Osteoplastics LLC ("Osteoplastics"), filed a lawsuit against the Company in the United States District Court for the District of Delaware, and Osteoplastics amended its complaint on April 2, 2020. Osteoplastics alleges that the Company's proprietary software, including the Company's iFit software platform, and the Company's use of its proprietary software for designing and manufacturing medical devices, including implants, infringes seven patents owned by Osteoplastics. On June 15, 2020, the Company filed a motion to dismiss Osteoplastics' complaint, and on October 21, 2020, the court denied the motion to dismiss. On November 2, 2020, the Company filed its answer to the amended complaint, denying that it infringes the patents asserted by Osteoplastics. The Company's answer also alleges the affirmative defense that Osteoplastics' asserted patents are invalid. Discovery in the lawsuit has commenced.

On April 24, 2020, the Company filed a lawsuit against Wright Medical Technology, Inc. and Tornier, Inc. (together, "Wright Medical") in the United States District Court for the District of Delaware. The Company is seeking damages for Wright Medical's infringement of certain of the Company's patents related to patient-specific instrument and implant systems. The complaint alleges that Wright Medical's multiple lines of patient-specific shoulder instruments, as well as the implant components used in conjunction with them, infringe four of the Company's patents. The accused product lines include Wright Medical's Tornier Blueprint™ 3D Planning + PSI shoulder replacement systems. On December 14, 2020, Wright Medical filed its answer to the amended complaint, denying that its patient-specific instrument and implant systems infringe the patents asserted by the Company. Wright Medical's answer also alleges the affirmative defense that the Company's asserted patents are invalid. Discovery in the lawsuit has commenced.

On May 8, 2020, the Company and an individual plaintiff filed a lawsuit against Aetna, Inc. and Aetna Life Insurance Company (together, "Aetna") in the United States District Court for the District of Massachusetts seeking damages for Aetna's improper denial of coverage for personalized knee implants under its health plans and the ones it administers. The Company amended its complaint on August 13, 2020, alleging that Aetna has violated its duties under state and federal law, including the Employee Retirement Income Security Act. On August 27, 2020, Aetna filed a motion to dismiss the amended complaint. The court has not yet ruled on the motion.

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.

Legal costs associated with legal proceedings are accrued as incurred.

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these

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

Note I—Debt and Notes Payable

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

	December 31, 2020	December 31, 2019
PPP "Term Loan"	4,720	—
Innovatus, Term Loan	20,000	20,000
Innovatus, Term Loan accrued payment-in-kind interest	775	262
Less unamortized debt issuance costs	(492)	(639)
Long-term debt, less debt issuance costs	<u>\$ 25,003</u>	<u>\$ 19,623</u>

Principal payments due as of December 31, 2020 consisted of the following (in thousands):

	Principal Payment
2021	\$ —
2022	4,720
2023	8,986
2024	12,580
Total	<u>\$ 26,286</u>

2017 Secured Loan Agreement

On January 6, 2017, the Company entered into the 2017 Secured Loan Agreement with Oxford. Through the 2017 Secured Loan Agreement, the Company accessed \$15 million under Term Loan A at closing and an additional \$15 million of borrowings under Term Loan B on June 30, 2017. On December 13, 2018, the Company entered into a fifth amendment (the "Fifth Amendment") to the 2017 Secured Loan Agreement, 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 and final payment. Under the Fifth Amendment, the Company's cash collateral requirement was reduced to \$5 million. 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 to provide 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 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.

On July 1, 2020, the Company entered into a third amendment to its 2019 Secured Loan Agreement, which, among other things, waived the trailing six-month revenue covenant milestones that applied to the quarters ended June 30, September 30 and December 31, 2020 under the agreement, reduced the revenue covenant milestones that apply thereafter, and delays until June 25, 2021 the Company's option to prepay all, but not less than all, of the term loans advanced under the 2019 Secured Loan Agreement. On August 20, 2020, the Company entered into a fourth amendment to the 2019 Secured Loan Agreement, which, among other things, waived certain provisions of the 2019 Secured Loan Agreement that apply to Conformis India LLP. As of December 31, 2020, the Company was not in breach of covenants under the 2019 Secured Loan Agreement.

On March 1, 2021, the Company entered into a fifth amendment to the 2019 Secured Loan Agreement, which, among other things, waives the trailing six-month revenue covenant milestones that apply to the quarters ending March 31, June 30, September 30 and December 31, 2021 and reduces the revenue covenant milestones that apply in 2022. The revenue covenant milestones remain unchanged for 2023 and 2024. The amendment also increases the Company's minimum cash covenant to \$5 million until December 31, 2021.

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, 2020. 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, and except as noted above, 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, 2020.

PPP Loan - East West Bank

On April 17, 2020, the Company entered into an approximately \$4.7 million promissory note (the "PPP Note") with East West Bank under the Paycheck Protection Program ("PPP") offered by the U.S. Small Business Administration (the "SBA") to mitigate the negative financial and operational impacts of the COVID-19 pandemic. The interest rate on the PPP Note is a fixed rate of 1% per annum. The Company is required to make one payment of all outstanding principal plus all accrued unpaid interest on April 9, 2022 (the "Maturity Date"). The Company will pay regular monthly payments in an amount equal to one month's accrued interest commencing on August 2, 2021, with all subsequent interest payments to be due on the same day of each month after that. All interest which accrues during the deferral period will be payable on the Maturity Date. According to the terms of the PPP, all or a portion of the loan as well as any accrued interest may be fully forgiven if the funds are used for payroll costs (and at least 60% of the forgiven amount must have been used for payroll), interest on certain other outstanding debt, rent, and utilities. In accordance with the CARES Act, the Company used the proceeds of the loan primarily for payroll costs. The Company submitted the loan forgiveness application to the lender on December 11, 2020. The Company resubmitted the application on February 23, 2021 with additional supporting documentation as requested by the lender. The Company is currently waiting for a final decision from the lender regarding approval of the application. The Company accounts for the PPP Note as a debt instrument in accordance with ASC 470-50-40-2, with the proceeds from the loan recognized as a long-term liability, less any debt issuance costs, within the consolidated balance sheet. Interest is accrued at the stated rate on a monthly basis by applying the interest method under ASC 835.

Note J—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 which the Company agreed to issue and sell to the Innovatus Investors an aggregate of 775,194 shares of the Company's common stock, par value \$0.00001 per share (the "Shares"), in a private placement (the "Private Placement"). The Innovatus 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, 2020 and December 31, 2019.

Demand registration rights

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.

Shelf registration

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 an Equity Distribution Agreement

("Distribution Agreement") with Canaccord Genuity LLC (formerly, Canaccord Genuity Inc.) ("Canaccord") pursuant to which Canaccord agreed to sell shares of the Company's common stock from time to time, as its agent, in an "at-the-market" ("ATM") offering as defined in Rule 415 promulgated under the U.S. Securities Act of 1933, as amended (the "Securities Act"). The Company was not obligated to sell any shares under the Distribution Agreement. On August 4, 2020, the Company and Canaccord mutually agreed to terminate the Distribution Agreement and as of that date, the Company had sold 2,663,000 shares under the Distribution Agreement resulting in net proceeds of \$4.4 million.

On March 23, 2020, the Company filed a new shelf registration statement on Form S-3 (the "New Shelf Registration Statement"), which was declared effective by the SEC on August 5, 2020. Under the New Shelf Registration Statement, the Company is permitted 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 August 5, 2020, the Company filed with the SEC a prospectus supplement, for the sale and issuance of up to \$25 million of its common stock and entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") pursuant to which the Company may offer and sell shares of the Company's common stock to or through Cowen, acting as agent and/or principal, from time to time, in an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act, including without limitation sales made by means of ordinary brokers' transactions on the NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by the Company. Cowen will use commercially reasonable efforts to sell the Common Stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay Cowen a commission of up to 3.0% of the gross sales proceeds of any Common Stock sold through Cowen under the Sales Agreement, and we also provided Cowen with customary indemnification rights. The shares of Common Stock being offered pursuant to the Sales Agreement will be offered and sold pursuant to the New Shelf Registration Statement. The Company is not obligated to make any sales of Common Stock under the Sales Agreement. The offering of shares of Common Stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all Common Stock subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms. As of December 31, 2020, the Company had not sold any shares under the Sales Agreement.

Stock purchase agreement

On December 17, 2018, the Company entered into a stock purchase agreement (the "Stock Purchase Agreement") with Lincoln Park Capital ("LPC"). Upon entering into the Stock Purchase 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. As consideration for LPC's commitment to purchase shares of common stock under the Stock Purchase Agreement, the Company issued 354,430 shares to LPC. The Company has the right at its sole discretion to sell to LPC up to \$20.0 million worth of shares over a 36-month period subject to the terms of the Stock Purchase Agreement. The Company controls the timing of any sales to LPC and LPC will be obligated to make purchases of the Company's common stock upon receipt of requests from the Company in accordance with the terms of the Stock Purchase Agreement. There are no upper limits to the price per share LPC may pay to purchase up to \$20.0 million worth of common stock subject to the Stock Purchase 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 Stock Purchase Agreement, provided that LPC will not be obligated to make purchases of the Company's common stock pursuant to receipt of a request from the Company on any business day on which the last closing trade price of the Company's common stock on the NASDAQ Capital Market (or alternative national exchange in accordance with the Stock Purchase Agreement) is below a floor price of \$0.25 per share. No warrants, derivatives, financial or business covenants are associated with the Stock Purchase 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 Stock Purchase Agreement may be terminated by the Company at any time, at the Company's sole discretion, without any cost or penalty. On August 5, 2020, the Company filed with the SEC a prospectus supplement, for the sale and issuance of up to \$17.6 million of its common stock pursuant to the Stock Purchase Agreement dated December 17, 2018. As of December 31, 2020, the Company had sold 4,521,968 shares under the Stock Purchase Agreement resulting in proceeds of \$3.4 million.

Registered direct offering

On September 23, 2020, the Company and a healthcare-focused institutional investor entered into a subscription agreement, pursuant to which the Company sold (i) 8,512,088 shares of its common stock and

accompanying warrants to purchase up to 8,512,088 shares of common stock and (ii) pre-funded warrants to purchase up to 9,492,953 shares of common stock and accompanying warrants to purchase up to 9,492,953 shares of common stock in a registered direct offering for gross proceeds of approximately \$17.3 million. The common stock (or pre-funded warrants in lieu thereof) and accompanying warrants were sold as units, each consisting of one share (or one pre-funded warrant to purchase one share of common stock in lieu thereof) and one warrant to purchase one share of common stock, at an offering price of \$0.9581 per unit.

The pre-funded warrants became exercisable immediately upon issuance, have an exercise price of \$0.0001 per share and will be exercisable until all of the pre-funded warrants are exercised in full. The warrants became exercisable immediately upon issuance, have an exercise price of \$0.8748 per share, and will expire five years from the date of issuance. The pre-funded warrants and the warrants each prohibit the holder from exercising any portion thereof to the extent that the holder would own more than 9.99% of the number of shares of common stock outstanding immediately after exercise. The number of shares issuable upon exercise of the warrants and pre-funded warrants and the exercise price of the warrants and pre-funded warrants is adjustable in the event of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The net proceeds to the Company from the offering, after deducting the placement agent's fees and other estimated offering expenses payable by the Company, was approximately \$15.9 million.

Warrants

The Company has issued warrants to certain investors and consultants to purchase shares of the Company's common stock. Based on the Company's assessment of the warrants granted in 2013 and 2014 relative to ASC 480, *Distinguishing Liabilities from Equity*, such warrants are classified as equity. According to ASC 480, an entity shall classify as a liability any financial instrument, other than an outstanding share, that, at inception, both a) embodies an obligation to repurchase the issuer's equity shares, or is indexed to such obligation and b) requires or may require the issuer to settle the obligation by transferring assets. The warrants do not contain any provision that requires the Company to repurchase the shares and are not indexed to such an obligation. The warrants also do not require the Company to settle by transferring assets. All warrants were exercisable immediately upon issuance.

In connection with the September 23, 2020 registered direct offering, the Company issued 9,492,953 pre-funded common stock warrants with an exercise price of \$0.0001 per share and an additional 18,005,041 common stock warrants with an exercise price of \$0.8748 per share. All of the warrants are exercisable for one share of common stock and are exercisable immediately. As of March 3, 2021, approximately 6.0 million of the common stock warrants have been exercised. The pre-funded warrants are exercisable indefinitely, while the additional warrants are exercisable for 5 years from the date of issuance. As of December 31, 2020, all pre-funded warrants were exercised. Based on the Company's assessment of the warrants granted relative to ASC 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, these warrants are classified as equity instruments. The fair value of the common stock warrants of approximately \$10.2 million at the date of issuance was estimated using the Black-Scholes model which used the following inputs: term of 5 years, risk free rate of 0.28%, 0% dividend yield, volatility of 90.15%, an exercise price of \$0.875 and share price of \$0.833 per share based on the trading price of the Company's common stock.

Warrants to purchase 18,025,967 shares of common stock were outstanding as of December 31, 2020 and warrants to purchase 28,926 shares were outstanding as of December 31, 2019. Outstanding common stock warrants are currently exercisable with varying exercise expiration dates from 2024 through 2025, and outstanding pre-funded warrants are exercisable until all of the pre-funded warrants are exercised in full. As of December 31, 2020, all pre-funded warrants have been exercised. At December 31, 2020 and 2019, the weighted average warrant exercise price per share for common stock and pre-funded warrants underlying the warrants and the weighted average contractual life was as follows:

	Number of Common Stock Warrants	Number of Pre- funded Warrants	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life	Number of Warrants Exercisable	Weighted Average Price Per Share
Outstanding December 31, 2019	28,926	—	\$ 9.8	3.66	28,926	\$ 9.8
Granted	18,005,041	—	\$ 0.88	4.73	18,005,041	\$ 0.88
Granted- pre-funded warrants	—	9,492,953	\$ 0.0001	—	9,492,953	\$ 0.0001
Exercised	—	(9,492,953)	—	—	(9,492,953)	—
Cancelled/expired	(8,000)	—	—	—	(8,000)	—
Outstanding December 31, 2020	18,025,967	—	\$ 0.89	4.73	18,025,967	\$ 0.89

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. Effective January 1, 2020, an additional 2,112,822 shares of the Company's common stock were added to the 2015 Plan under the terms of this provision. As of December 31, 2020, 275,439 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, 2020, 2,771,481 shares of common stock were available for future issuance 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, 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
Granted	452,129	0.82	
Exercised	—		—
Expired	(474,580)	7.14	
Cancelled/Forfeited	(12,433)	1.39	
Outstanding December 31, 2020	1,767,579	\$ 5.16	\$ —
Total vested and exercisable	1,245,972	\$ 6.80	\$ —

The total fair value of stock options that vested during the year ended December 31, 2020 was \$0.5 million. The weighted average remaining contractual term for the total stock options outstanding was 5.51 years at December 31, 2020. The weighted average remaining contractual term for the total stock options vested and exercisable was 3.97 years at December 31, 2020.

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

	Number of Shares	Weighted Average Fair Value
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
Granted	4,351,758	0.95
Vested	(1,882,094)	1.56
Forfeited	(630,553)	1.01
Unvested December 31, 2020	6,276,039	\$ 1.18

The total fair value of restricted common stock awards that vested during the year ended December 31, 2020 was \$2.9 million.

Inducement Awards

In February 2020, the Company granted inducement awards outside of the 2015 Plan and 2019 Sales Team Plan (i) to the Company's Chief Financial Officer in the form of an option to purchase 125,000 shares of the Company's common stock with an exercise price per share equal to \$0.98 and 125,000 restricted stock units and (ii) to the Company's Senior Vice President, Operations in the form of an option to purchase 66,667 shares of the Company's common stock with an exercise price per share equal to \$0.98 and 61,350 restricted stock units. The

option and restricted stock unit awards were granted as inducements material to their commencement of employment with the Company in accordance with NASDAQ Listing Rule 5635(c)(4).

In August 2020, the Company granted inducement awards outside of the 2015 Plan and 2019 Sales Team Plan to the Company's Vice President, US Marketing in the form of an option to purchase 100,000 shares of the Company's common stock with an exercise price per share equal to \$0.7427 and 100,000 restricted stock units. The option and restricted stock unit awards were granted as inducements material to his commencement of employment with the Company in accordance with NASDAQ Listing Rule 5635(c)(4).

In November 2020, the Company granted inducement awards outside of the 2015 Plan and 2019 Sales Team Plan to the Company's Vice President, International Sales and Marketing in the form of 75,000 restricted stock units. The restricted stock unit awards were granted as inducements material to his commencement of employment with the Company in accordance with NASDAQ Listing Rule 5635(c)(4).

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. The valuation of the Company's common stock prior to its initial public offering was performed with the assistance of an independent third-party valuation firm using a methodology that includes various inputs including the Company's historical and projected financial results, peer company public data and market metrics, such as risk-free interest and discount rates. 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 \$0.47 and \$1.44 for the year ended December 31, 2020 and 2019, 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,	
	2020	2019
Risk-free interest rate	1.14%	1.89%
Expected term (in years)	6.16	6.00
Dividend yield	—%	—%
Expected volatility	54.89%	55.80%

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 has limited history of market prices of its common stock over the historical period equal in length to the expected term, and may sometimes estimate volatility using historical volatilities of similar public entities.

Forfeitures. The Company recognizes forfeitures as they occur.

Stock-based compensation expense was \$3.4 million and \$2.8 million for the years ended December 31, 2020 and 2019, 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,	
	2020	2019
Cost of revenue	\$ 72	\$ 350
Sales and marketing	446	213
Research and development	648	565
General and administrative	2,240	1,709
	<u>\$ 3,406</u>	<u>\$ 2,837</u>

At December 31, 2020, the Company had \$0.2 million of total unrecognized compensation expense for options that will be recognized over a weighted average period of 1.99 years. At December 31, 2020, the Company had \$5.7 million of total unrecognized compensation expense for restricted awards recognized over a weighted average period of 2.35 years.

Note K—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, 2020 and 2019 includes the following components (in thousands):

	Years ended December 31,	
	2020	2019
Loss before income taxes:		
U.S.	\$ (21,968)	\$ (25,814)
Non-U.S.	(2,283)	(2,619)
	<u>\$ (24,251)</u>	<u>\$ (28,433)</u>

Significant components of the provision for income taxes for the years ended December 31, 2020 and 2019 were as follows (in thousands):

	Years ended December 31,	
	2020	2019
Current:		
Federal	\$ —	\$ —
State	9	11
Foreign	33	34
	<u>42</u>	<u>45</u>
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
	<u>—</u>	<u>—</u>
Total	<u>\$ 42</u>	<u>\$ 45</u>

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,			
	2020		2019	
Tax at U.S. statutory rate	21.00	%	21.00	%
State taxes, net of federal benefits	3.68		10.07	
Permanent items	(1.07)		(9.25)	
Tax credit	0.37		(3.08)	
Change in valuation allowance	(25.37)		(21.90)	
Foreign rate differential	0.76		0.71	
Rate change	(0.69)		(1.05)	
Uncertain tax positions	4.22		5.65	
NQ Stock option expirations & forfeitures	(0.09)		(2.53)	
Other	(2.98)		0.22	
	(0.17)	%	(0.16)	%

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,	
	2020	2019
Deferred tax assets:		
Federal and state net operating loss carryforwards	\$ 23,124	\$ 16,890
Foreign net operating loss carryforwards	6,312	5,080
Accrued expenses	380	249
Credits	7,429	7,519
Intangibles	1,278	1,355
Stock compensation expense	988	1,324
Lease liability	1,327	1,653
Other	3,568	3,750
Total deferred tax assets	44,406	37,820
Valuation allowance	(41,507)	(35,347)
Net deferred tax assets	2,899	2,473
Deferred tax liabilities:		
Fixed assets	(914)	(994)
Right of use asset	(1,175)	(1,479)
Other	(810)	—
Net deferred tax liabilities	(2,899)	(2,473)
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 \$41.5 million valuation allowance at December 31, 2020 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, 2020, the Company had approximately \$439.5 million of federal net operating loss carryforwards of which \$379.8 million if not utilized, will begin to expire in 2021 for federal tax purposes, while \$59.7 million of the total will not expire, and approximately \$243.9 million of state net operating loss carryforwards that if not utilized, will continue to expire at various dates starting 2021 for state tax purposes. The Company also has federal and state tax credits of \$5.4 million and \$2.5 million, which begin to expire in 2021 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, 2020. The limitations may reduce the amount of federal and state NOLs and credits of \$439.5 million and \$243.9 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 \$33.5 million as of December 31, 2020, which may be available to offset future income recognized in the Federal Republic of Germany, India and the United Kingdom. The net operating losses in Germany and the United Kingdom have indefinite carryforward periods, while India carryforward period is eight years.

The Company has adopted the accounting guidance related to uncertainty in income taxes. The total liability for unrecognized income tax benefits was approximately \$4.1 million and \$5.1 million as of December 31, 2020 and 2019, respectively. Of the total liability at December 31, 2020 and 2019, \$3.7 million and \$6.4 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 believes that it is reasonably possible a decrease of up to \$1.2 million in unrecognized tax benefits, as a result of a lapse of the statute of limitations in Germany, will occur within the coming 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.

	<u>Years ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
Unrecognized tax benefits beginning of year	\$ 5,118	\$ 6,764
Gross change for current year positions	722	836
Increase for prior period positions	29	—
Decrease for prior period positions	(495)	—
Decrease due to statute limitations	(1,280)	(2,482)
Unrecognized tax benefits end of the year	<u>\$ 4,094</u>	<u>\$ 5,118</u>

As of December 31, 2020, 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, 2020, 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 L—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 and equipment are based upon physical location of the assets.

Geographic information consisted of the following (in thousands):

	Years Ended December 31,	
	2020	2019
Product Revenue		
United States	\$ 50,736	\$ 67,151
Germany	6,526	7,598
Rest of World	1,278	1,900
	<u>\$ 58,540</u>	<u>\$ 76,649</u>

	December 31,	
	2020	2019
Property and equipment, net		
United States	\$ 12,195	\$ 13,303
Rest of World	45	53
	<u>\$ 12,240</u>	<u>\$ 13,356</u>

Note M —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 \$0.5 million and \$0.4 million to the plan during the years ended December 31, 2020 and 2019, respectively.

Note N —Selected Quarterly Financial Information (Unaudited)

(in thousands, except per share data)	Three Months Ended			
	December 31, 2020	September 30, 2020	June 30, 2020	March 31, 2020
Total revenue	\$ 16,697	\$ 16,121	\$ 19,468	\$ 16,475
Gross profit	7,799	7,684	11,018	7,214
Net loss	(6,622)	(6,183)	(2,135)	(9,353)
Net loss per share - basic and diluted	\$ (0.08)	\$ (0.09)	\$ (0.03)	\$ (0.14)

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

Note O—Subsequent Events

2021 Common Stock Offering

On February 17, 2021, the Company closed an offering of its common stock off of the Shelf Registration Statement and issued and sold 80,952,381 shares of its common stock at a public offering price of \$1.05 per share,

for aggregate net proceeds of approximately \$79.6 million. The Company intends to use the net proceeds of the offering of the shares for general corporate purposes, which may include research and development costs, sales and marketing costs, clinical studies, manufacturing development, the acquisition or licensing of other businesses or technologies, repayment and refinancing of debt, including the Company's secured term loan facility, working capital and capital expenditures.

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, 2020. 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, 2020, 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, 2020. 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, 2020, 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, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On March 1, 2021, we entered into a fifth amendment to the 2019 Secured Loan Agreement, which, among other things, waives the trailing six-month revenue covenant milestones that apply to the quarters ending March 31, June 30, September 30 and December 31, 2021 and reduces the revenue covenant milestones that apply in 2022. The revenue covenant milestones remain unchanged for 2023 and 2024. The amendment also increases our minimum cash covenant to \$5 million until December 31, 2021. For further information regarding the 2019 Secured Loan Agreement and the fifth amendment, see "Note I—Debt and Notes Payable" in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. The fifth amendment to the 2019 Secured Loan Agreement is attached in full as Exhibit 10.56.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Directors and Executive Officers

The information required by this item will be set forth in our Proxy Statement for the 2021 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 Capital 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 2021 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 2021 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 Capital Market.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be set forth in our Proxy Statement for the 2021 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 2021 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 2021 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 2021 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. Consolidated Financial Statement

For a list of consolidated financial statements included herein, see Index to the Consolidated Financial Statements on page 78 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 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 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 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 (incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed on March 3, 2020)
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 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)

- [10.15^](#) [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\)](#)
- [10.16](#) [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\)](#)
- [10.17](#) [First Amendment to Lease dated July 25, 2016 between Wakefield Investments, Inc. and Registrant for 600 Research Drive, Wilmington, Massachusetts \(incorporated herein by reference to Exhibit 10.26 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed on March 8, 2017\)](#)
- [10.18](#) [Lease dated September 19, 2016 between Technology Park I Limited Partnership and Registrant for 600 Technology Park Drive, Billerica, Massachusetts \(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the fiscal year ended September 30, 2016, filed on November 10, 2016\)](#)
- [10.19](#) [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\)](#)
- [10.20†](#) [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\)](#)
- [10.21](#) [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\)](#)
- [10.22^](#) [Employment Agreement, dated October 19, 2016, by and between the Registrant and Mark A. Augusti, as amended and restated effective December 2, 2016 \(incorporated herein by reference to Exhibit 10.34 of the Registrant's Annual Report on Form 10-K for the period ended December 31, 2016, filed with the Securities and Exchange Commission on March 8, 2017\)](#)
- [10.23†](#) [Asset Purchase Agreement dated August 9, 2017, by and between Conformis, Inc. and Broad Peak Manufacturing, LLC \(incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2017, filed on November 9, 2017\)](#)
- [10.24^](#) [Amendment to Employment Agreement dated September 14, 2017, by and between Conformis, Inc. and Mark Augusti, its President and Chief Executive Officer \(incorporated herein by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2017, filed on November 9, 2017\)](#)
- [10.25^](#) [Second Amendment to Amended and Restated Employment Agreement dated July 31, 2018, by and between Conformis, Inc. and Mark Augusti, its Chief Executive Officer \(incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2018, filed on August 2, 2018\)](#)
- [10.26†](#) [Settlement and License Agreement dated September 14, 2018 between Conformis, Inc. and Smith & Nephew, Inc. \(incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2018, filed on November 5, 2018\)](#)
- [10.27](#) [Purchase Agreement dated December 17, 2018 by and between Conformis, Inc. and Lincoln Park Capital Fund, LLC \(incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 18, 2018\)](#)
- [10.28](#) [Registration Rights Agreement dated December 17, 2018 by and between Conformis, Inc. and Lincoln Park Capital Fund, LLC \(incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 18, 2018\)](#)
- [10.29^](#) [Third Amendment to Employment Agreement dated March 8, 2019, by and between Conformis, Inc. and March Augusti, its President and Chief Executive Officer \(incorporated herein by reference to Exhibit 10.46 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed on March 13, 2019\)](#)

- [10.30^](#) [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 for the Registrant's 2019 Annual Meeting of Stockholders filed on March 15, 2019\)](#)
- [10.31](#) [Loan and Security Agreement, dated as of June 25, 2019, by and among Conformis, Inc. and the other parties thereto. \(incorporated hereby by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on June 26, 2019\)](#)
- [10.32](#) [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 \(incorporated hereby by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on June 26, 2019\)](#)
- [10.33](#) [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 \(incorporated hereby by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on June 26, 2019\)](#)
- [10.34^](#) [Employment Agreement dated July 29, 2019, by and between Conformis, Inc. and J. Brent Alldredge, its Chief Legal Officer and Corporate Secretary. \(incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 filed on August 2, 2019\)](#)
- [10.35](#) [First Amendment to Loan and Security Agreement, dated as of August 15, 2019, by and among Conformis, Inc. and the other parties thereto \(incorporated herein by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 filed on November 1, 2019\)](#)
- [10.36†](#) [Asset Purchase Agreement, dated as of September 30, 2019, by and between Howmedica Osteonics Corp. and Conformis, Inc. \(incorporated herein by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 filed on November 1, 2019\)](#)
- [10.37†](#) [Distribution Agreement, dated as of September 30, 2019, by and between Howmedica Osteonics Corp. and Conformis, Inc. \(incorporated herein by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 filed on November 1, 2019\)](#)
- [10.38†](#) [License Agreement, dated as of September 30, 2019, by and between Howmedica Osteonics Corp. and Conformis, Inc. \(incorporated herein by reference to Exhibit 10.5 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 filed on November 1, 2019\)](#)
- [10.39†](#) [Development Agreement, dated as of September 30, 2019, by and between Howmedica Osteonics Corp. and Conformis, Inc. \(incorporated herein by reference to Exhibit 10.6 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 filed on November 1, 2019\)](#)
- [10.40†](#) [First Amendment to Asset Purchase Agreement, dated as of October 23, 2019, by and between Howmedica Osteonics Corp. and Conformis, Inc. \(incorporated herein by reference to Exhibit 10.7 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 filed on November 1, 2019\)](#)
- [10.41^](#) [Form of 2015 Stock Incentive Plan Performance-Vested Restricted Stock Agreement \(incorporated herein by reference to Exhibit 10.8 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 filed on November 1, 2019\)](#)
- [10.42^](#) [Form of 2019 Sales Team Performance-Based Equity Incentive Plan Performance-Vested Restricted Stock Agreement \(incorporated herein by reference to Exhibit 10.9 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 filed on November 1, 2019\)](#)
- [10.43^](#) [Fourth Amendment to Amended and Restated Employment Agreement dated November 2, 2019, by and between Conformis, Inc. and Mark Augusti, its Chief Executive Officer \(incorporated herein by reference to Exhibit 10.59 of the Registrant's Form 10-K for the fiscal year ended December 31, 2020 filed on March 3, 2020\)](#)

- [10.44^](#) [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 \(incorporated herein by reference to Exhibit 10.61 of the Registrant's Form 10-K for the fiscal year ended December 31, 2020 filed on March 3, 2020\)](#)
- [10.45^](#) [Form of 2015 Stock Incentive Plan Restricted Stock Grant for Independent Sales Representative \(incorporated herein by reference to Exhibit 10.62 of the Registrant's Form 10-K for the fiscal year ended December 31, 2020 filed on March 3, 2020\)](#)
- [10.46^](#) [Form of Inducement Restricted Stock Unit Agreement \(incorporated herein by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 filed on March 3, 2020\)](#)
- [10.47^](#) [Form of Inducement Incentive Grant Agreement \(incorporated herein by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 filed on March 3, 2020\)](#)
- [10.48^](#) [Fifth Amendment to Amended and Restated Employment Agreement dated February 4, 2020, by and between Conformis, Inc. and Mark Augusti, its Chief Executive Officer \(incorporated herein by reference to Exhibit 10.65 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2019\)](#)
- [10.49^](#) [Form of 2020 Incentive Compensation Program Award Letter \(incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 5, 2020\)](#)
- [10.50^](#) [Employment Agreement, effective as of February 17, 2020, by and between Conformis, Inc. and Robert Howe, its Chief Financial Officer \(incorporated herein by reference to Exhibit 10.67 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2019\)](#)
- [10.51](#) [Second Amendment to Loan and Security Agreement, dated as of March 1, 2020, by and among Conformis, Inc. and the other parties thereto \(incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2020 filed on May 11, 2020\)](#)
- [10.52](#) [Consent Under Loan and Security Agreement, dated as of April 17, 2020, by and among Conformis, Inc. and the other parties thereto \(incorporated herein by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2020 filed on May 11, 2020\)](#)
- [10.53](#) [Third Amendment, dated July 1, 2020, to Loan and Security Agreement by and between Conformis, Inc., ImaTx, Inc., Conformis Cares LLC and Innovatus Life Sciences Lending Fund I, LP \(incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K \(File No. 001-37474\) filed on July 6, 2020\)](#)
- [10.54](#) [Form of Global Restricted Stock Agreement under 2015 Stock Incentive Plan \(incorporated herein by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2020 filed on August 5, 2020\)](#)
- [10.55](#) [Fourth Amendment, dated August 20, 2020, to Loan and Security Agreement by and between Conformis, Inc., ImaTx, Inc., Conformis Cares LLC and Innovatus Life Sciences Lending Fund I, LP \(incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2020 \(File No. 001-37474\) filed on November 4, 2020\)](#)
- [10.56*](#) [Fifth Amendment dated March 1, 2021 to Loan and Security Agreement by and between Conformis, Inc., ImaTx, Inc., Conformis Cares LLC and Innovatus Life Sciences Lending Fund I, LP](#)
- [21.1*](#) [Subsidiaries of the Registrant](#)
- [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

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- * 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: 3/3/2021

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
<u>/s/Mark A. Augusti</u> Mark A. Augusti	President and Chief Executive Officer (Principal Executive Officer) and Director	3/3/2021
<u>/s/Robert Howe</u> Robert Howe	Chief Financial Officer (Principal Financial Officer) and Principal Accounting Officer	3/3/2021
<u>/s/Kenneth Fallon III</u> Kenneth Fallon III	Chairman of the Board of Directors	3/3/2021
<u>/s/Philip W. Johnston</u> Philip W. Johnston	Director	3/3/2021
<u>/s/Carrie Bienkowski</u> Carrie Bienkowski	Director	3/3/2021
<u>/s/Bradley Langdale</u> Bradley Langdale	Director	3/3/2021
<u>/s/Richard Meelia</u> Richard Meelia	Director	3/3/2021
<u>/s/Michael Milligan</u> Michael Milligan	Director	3/3/2021

FIFTH AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FIFTH AMENDMENT to Loan and Security Agreement (this “**Amendment**”) is entered into as of March 1, 2021, by and among INNOVATUS LIFE SCIENCES LENDING FUND I, LP, a Delaware limited partnership, as collateral agent (in such capacity, together with its successors and assigns in such capacity, “**Collateral Agent**”), and CONFORMIS, INC., a Delaware corporation, IMATX, Inc., a California corporation and Conformis Cares LLC, a Delaware limited liability company (individually and collectively, jointly and severally, “**Borrower**”).

WHEREAS, Collateral Agent, Borrower and Lenders have entered into that certain Loan and Security Agreement, dated as of June 25, 2019 (as amended, supplemented or otherwise modified from time to time, the “**Loan Agreement**”) pursuant to which Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof; and

WHEREAS, Borrower, Required Lenders and Collateral Agent desire to amend certain provisions of the Loan Agreement as set forth herein.

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower, Required Lenders and Collateral Agent hereby agree as follows:

1. Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Loan Agreement.
2. Section 6.12 of the Loan Agreement is hereby amended and restated as follows:

6.12 Financial Covenant. Borrower shall achieve the following minimum T6M Product Revenue at the end of each of the following quarters:

<u>Quarter Ending</u>	<u>Minimum T6M Product Revenue in millions</u>
December 31, 2019	\$32.5
March 31, 2020	\$36.0
June 30, 2020	Waived
September 30, 2020	Waived
December 31, 2020	Waived
March 31, 2021	Waived
June 30, 2021	Waived
September 30, 2021	Waived
December 31, 2021	Waived
March 31, 2022	\$32.0
June 30, 2022	\$33.0
September 30, 2022	\$36.0
December 31, 2022	\$41.0
March 31, 2023	\$43.5
June 30, 2023	\$43.5
September 30, 2023	\$43.5
December 31, 2023	\$45.5
March 31, 2024	\$46.0

Notwithstanding anything herein to the contrary, Borrower shall not be obligated to comply with the provisions of this Section 6.12 for the quarter immediately following any quarter at the end of which (i) the T6M Product Revenue of Borrower, as determined by Collateral Agent was at least \$45.0 million and (ii) Borrower has been cash flow positive for two successive quarters.

3. Section 6.13 of the Loan Agreement is hereby amended and restated as follows:

6.13 Liquidity Covenant. Borrower shall at all times maintain in a Collateral Account at Bank or subject to a Control Agreement in favor of Collateral Agent a cash balance of not less than an amount equal to the lesser of (i) the Minimum Cash Amount or (ii) the Minimum Cash Elected Amount. Notwithstanding the foregoing, commencing on July 1, 2020, Borrower shall at all times, until December 31, 2021, maintain in a Collateral Account at Bank or subject to a Control Agreement in favor of Collateral Agent a cash balance of not less than Five Million Dollars (\$5,000,000.00).

4. Limitation of Amendment.

- a. The amendments set forth above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right, remedy or obligation which Lenders or Borrower may now have or may have in the future under or in connection with any Loan Document, as amended hereby.
- b. This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, are hereby ratified and confirmed and shall remain in full force and effect.

5. To induce Collateral Agent and Required Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Required Lenders as follows:

- a. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default (other than the Potential Event of Default) has occurred and is continuing;
- b. Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;
- c. The organizational documents of Borrower delivered to Collateral Agent on the Effective Date, and updated pursuant to subsequent deliveries by or on behalf of the Borrower to the Collateral Agent, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;
- d. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not contravene (i) any material law or regulation binding on or affecting Borrower, (ii) any material contractual restriction with a Person binding on Borrower, (iii) any material order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (iv) the organizational documents of Borrower;
- e. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any

order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

- f. This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.
6. Except as expressly set forth herein, the Loan Agreement shall continue in full force and effect without alteration or amendment. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.
7. The Borrower hereby remises, releases, acquits, satisfies and forever discharges the Lenders and Collateral Agent, their agents, employees, officers, directors, predecessors, attorneys and all others acting or purporting to act on behalf of or at the direction of the Lenders and Collateral Agent ("**Releasees**"), of and from any and all manner of actions, causes of action, suit, debts, accounts, covenants, contracts, controversies, agreements, variances, damages, judgments, claims and demands whatsoever, in law or in equity, which any of such parties ever had, now has or, to the extent arising from or in connection with any act, omission or state of facts taken or existing on or prior to the date hereof, may have after the date hereof against the Releasees, for, upon or by reason of any matter, cause or thing whatsoever relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof through the date hereof. Without limiting the generality of the foregoing, the Borrower waives and affirmatively agrees not to allege or otherwise pursue any defenses, affirmative defenses, counterclaims, claims, causes of action, setoffs or other rights they do, shall or may have as of the date hereof, including the rights to contest: (a) the right of Collateral Agent and each Lender to exercise its rights and remedies described in the Loan Documents; (b) any provision of this Amendment or the Loan Documents; or (c) any conduct of the Lenders or other Releasees relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof.
8. This Amendment shall be deemed effective as of the date first set forth above upon the due execution and delivery to Collateral Agent of this Amendment by each party hereto.
9. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument.
10. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of New York.

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IN WITNESS WHEREOF, the parties hereto have caused this Fifth Amendment to Loan and Security Agreement to be executed as of the date first set forth above.

BORROWER:

CONFORMIS, INC.

By: /s/ Mark Augusti
Name: Mark Augusti
Title: President & Chief Executive Officer

BORROWER:

IMATX, INC.

By: /s/ Mark Augusti
Name: Mark Augusti
Title: President & Treasurer

BORROWER:

CONFORMIS CARES LLC

By: /s/ Mark Augusti
Name: Mark Augusti
Title: President & Chief Financial Officer

COLLATERAL AGENT AND REQUIRED LENDER:

INNOVATUS LIFE SCIENCES LENDING FUND I, LP

By: Innovatus Life Sciences GP, LP
Its: General Partner

By: /s/ Andrew Hobson
Name: Andrew Hobson
Title: Authorized Signatory

Subsidiaries of the Registrant

Name	Jurisdiction of Organization
Conformis Cares LLC	Delaware
ConforMIS Europe GmbH	Germany
ConforMIS Hong Kong Limited	Hong Kong
Conformis India LLP	India
ConforMIS UK Limited	United Kingdom
ImaTX, Inc.	California

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 3, 2021, 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, 2020. We consent to the incorporation by reference of said report in the Registration Statements of Conformis, Inc. on Forms S-8 (File No. 333-249865, File No. 333-241109, File No. 333-236850, File No. 333-236849, File No. 333-231211, File No. 333-229215, File No. 333-223802, File No. 333-217872 and File No. 333-205477) and on Forms S-3 (File No. 333-25464 and File No. 333-237351).

/s/ GRANT THORNTON LLP

Boston, Massachusetts
March 3, 2021

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: 3/3/2021

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

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: 3/3/2021

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

**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, 2020 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: 3/3/2021

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

**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, 2020 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: 3/3/2021

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