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, 2022

OR

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

For the transition period from to

Commission file number: 001-37474

Conformis, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**56-2463152**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
600 Technology Park Drive Billerica, MA	**01821**
(Address of principal executive offices)	(Zip Code)

(781) 345-9001

(Registrant's telephone number, including area code)

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

Title of 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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. Yes ☑ No ☐

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 $63,300,326. As of February 28, 2023 there were 7,495,698 shares of the registrant's Common Stock, $0.00001 par value per share, outstanding. The number of shares outstanding takes in account the 1-for-25 reverse stock split that was consummated on November 9, 2022.

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, 2022. 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, projected reimbursement changes, 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. All references to common stock, share and per share amounts have been retroactively restated to reflect the 1-for-25 reverse stock split of our common stock that was approved by stockholders on October 26, 2022, and was consummated on November 9, 2022.

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

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

- our estimates regarding the potential market opportunity and timing of estimated commercialization for our current and future products, including our iUni, iDuo, iTotal CR, iTotal PS, iTotal Identity, Identity Imprint, Cordera hip system, Actera Hip System and the planned launch of our new product extensions, including the cementless option of the Identity Imprint knee platform and our Platinum Services℠ Program;
- our expectations regarding the transition of our U.S. knee implant business to Identity Imprint™ and our new Image-to-Implant® Platinum Services℠ Program offering, and related operational and regulatory risks we may be exposed to as a result of such transition;
- whether our capital resources will be adequate to meet the needs of our business and our ability to raise any additional capital;
- our ability to continue as a going concern;
- 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 successfully develop and commercialize planned products and services;
- 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;
- litigation claims against Aetna;
- 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 United States ("U.S.") and international businesses, including regulations of the U.S. Food and Drug Administration (the"FDA") and foreign government regulators, such as more stringent requirements for regulatory clearance of our products;
- potential further negative impacts related to the COVID-19 pandemic, including with respect to the magnitude of further resurgent case waves, the effectiveness of vaccines against current and future variant strains and public adoption rates of vaccines (including booster shots), and the actions that we have taken and are planning in response, including our ability to continue production and manufacturing activities at desired levels, the reliability of our supply chain, the pandemic's effect on labor conditions, 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; and
- our ability to satisfy all applicable Nasdaq continued listing requirements.

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 herein.*

Risks related to our financial position.

a. We have incurred losses in the past and expect to continue to incur losses in the future.
b. We expect to incur substantial expenditures in the foreseeable future and may require additional capital to continue as a going concern. This capital might not be available on terms favorable to us or at all.
c. 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 are transitioning our U.S. knee implant business to Identity Imprint™ and our new Image-to-Implant® Platinum Services℠ Program offering, which may expose us to new operational and regulatory risks.
b. We have derived more than half of our revenue from sales of a limited portfolio of knee and hip replacement products to a small number of customers.
c. We may not be successful in the development of, obtaining regulatory clearance or certification for, or commercialization of, additional products.
d. We face competition from large, well-established companies as well as new market entrants.
e. In order to become profitable, we will need to scale our business model considerably through increased sales.
f. The success of our products is dependent on our ability to demonstrate their clinical benefits.
g. We are subject to cost-containment efforts of hospitals and other medical facilities and group purchasing organizations.
h. Our revenues depend upon prompt and adequate coverage and reimbursement from public and private insurers and national health systems.
i. 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.
j. We rely on a limited number of sales representatives and distributors to market and sell our products.
k. Technology changes and surgeon adaptation are uncertain and we may not accurately predict the changing demands by our customers. Robotic and cementless arthroplasty procedures are growing and we currently do not have these offerings. Augmented reality and advanced tracking technologies are in various stages of development and deployment. Our ability to maintain and/or grow surgeon users could be negatively impacted if we are not able to offer these or any other new options demanded by surgeons.

Global economic conditions may adversely affect our results of operations.

a. The COVID-19 pandemic may continue to adversely affect our business.
b. Our sales and marketing depends on working relationships with research & development 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, 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 us.

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.
e. The barrier-free trade of medical devices between the European Union and Switzerland under the Mutual Recognition Agreement (MRA) ceased to apply from May 26, 2021, which adversely affect our financial results and our operations in Switzerland.
f. The European Medical Device Regulation has created an uncertain and unpredicatable regaulatory framework for EU compliance that may negatively impact our ability to continue to market and distribute our products in the applicable countries.

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.
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. Our common stock could be delisted if we fail to maintain compliance with Nasdaq requirements.
b. The price of our common stock can be volatile and fluctuate substantially.
c. Our quarterly operating results are subject to substantial fluctuations.
d. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
e. 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.
f. Exclusive forum provisions could discourage lawsuits against us and our directors and officers.
g. 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 and innovator in the orthopedic industry since our founding in 2004. In particular, we believe that we are a leader in the development, manufacturing, and sales of patient-specific products and instrumentation that are individually sized and shaped to fit each patient's unique knee and hip anatomy. The worldwide market for knee and hip replacement products is approximately $17 billion annually. In the U.S., elective total joint procedures are shifting from hospitals to outpatient facilities and ambulatory surgery centers ("ASCs"). We believe that approximately 50% of all primary hip and knee procedures will be performed in ASCs within the next five years.

A key driver in the outpatient shift of orthopedic procedures is the ongoing changes by the Centers for Medicare & Medicaid Services ("CMS"). In recent years, CMS removed key musculoskeletal services from the inpatient-only list, including total knee arthroplasty in 2018 and total hip arthroplasty in 2020. CMS also continues to expand the ASCs covered procedure list, including total knee arthroplasty in 2020 and total hip arthroplasty in 2021. As healthcare costs rise, we believe that governments and government agencies, including CMS, are looking to reduce their healthcare expenditures markedly through reimbursement reductions and cost-shifting to patients.

On January 6, 2022, we announced the launch of our new Image-to-Implant® Platinum Services℠ Program, a premium service offering for the U.S. market. New to orthopedics, this program seeks to address the rapidly evolving demands of the healthcare marketplace where generic products are being commoditized and patients are increasingly willing to pay a premium for personalized treatment options. As of September 1, 2022, U.S. medical facility customers are only able to obtain our fully personalized iTotal Identity knee system through participation in our Image-to-Implant Platinum Services℠ Program.

Both Medicare and most commercial payors permit patients to pay out-of-pocket for certain non-covered, deluxe services. Through the Image-to-Implant® Platinum Services℠ Program, we are bringing this approach to orthopedics by enabling participating medical facilities to establish and offer patients an out-of-pocket services upgrade to obtain the Company's fully personalized iTotal Identity™ knee system. Combined with our new Made-to-Measure Identity Imprint™ knee system, we believe that we now address multiple market segments within knee arthroplasty:

- the Identity Imprint™ knee system provides a data-informed high-quality knee implant system that provides a level of personalization through its patient-specific instruments ("PSI") and proprietary algorithms for pre-surgical planning, but is only available in pre-designed standard sizes, all at a price comparable to standard off-the-shelf options; and

- the Image-to-Implant® Platinum Services℠ Program gives patients in the United States the opportunity to upgrade to a fully-personalized iTotal Identity™ knee implant system by paying an incremental deluxe services fee.

As of December 31, 2022, we had sold a total of more than 149,000 knee implants worldwide, including more than 123,000 total knee implants and 26,000 partial knee implants. In multiple clinical studies, iTotal CR, our cruciate-retaining total knee replacement implant, demonstrated superior clinical outcomes, including with respect to function, kinematics and objective functional measures, and greater patient satisfaction compared to those of standard, or off-the-shelf, implants that it was tested against. On August 16, 2021, the first procedure was performed using the Imprint knee replacement system. Imprint, available in both cruciate retaining ("CR") and posterior stabilized ("PS") implants, utilizes a proprietary algorithm to select the appropriate implant size from 12 standard sizes that most closely meet the geometric and anatomic requirements of the patient's knee based on the individual's CT scan. As with Conformis' personalized iTotal knee product line, Imprint uses Conformis' sterile Surgery-in-a-Box delivery system, which we believe provides ASCs and hospitals with greater procedural efficiency and improved sterilization cost savings over comparable systems. With the growing interest in our Imprint system from ASC customers, we have prioritized applying our porous-coated technology to the Imprint system which will be our first cementless TKA product offering. We are targeting a limited commercial launch of the porous-coated technology in the second half of 2023, however the launch may be delayed to the first half of 2024 due to regulatory and/or technical challenges.

On November 11, 2019, we entered full commercial launch of the Conformis personalized hip system, now branded as Cordera Rx. Since the launch of the personalized hip system, we have introduced multiple product line extensions including Cordera Standard, Cordera Pro and Cordera Match. In November 2022, we completed the first

procedure using our Actera™ Hip System, a second hip stem within our hip portfolio. The system, designed for hip reconstruction, uses the cutting-edge tri-taper stem design, and features a range of sizes and angles derived from our data analytics. This cementless hip stem component features a proximally coated titanium spray with a hydroxyapatite layer to encourage initial and long-term fixation. We believe that the system's tri-taper stem design will enable surgeons to treat a broader range of patient anatomies and the shorter length options offer easier access to the femur while maintaining the fixation and integrity required for long term success of the implant. For the initial limited launch, the Actera™ Hip System will feature a range of standard sizes in both stem and cup components. We plan to launch future Actera™ line extensions that will offer additional personalization options for surgeons to choose what best fits their patients, even for complex anatomies. The new system is currently rolling out to select sites across the U.S., and we currently anticipate the full commercial launch to occur in mid-2023.

As of January 31, 2023, we own or exclusively in-license a total of approximately 241 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 60 issued United States patents, 135 patents issued in countries outside the United States, and 46 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 currently marketed knee and hip replacement products and related design software have been cleared by the FDA under the premarket notification process of Section 510(k) of the federal Food, Drug, and Cosmetic Act (the "FDCA"). We 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, Brazil, Suriname, Australia, the United Arab Emirates, the Sultanate of Oman, Italy, 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 33 million people in the United States and over 500 million people worldwide suffer from osteoarthritis. We believe that compelling demographic trends, such as the growing population of aging yet active individuals and rising rates of obesity, will be key drivers in the continued growth of osteoarthritis occurrence. The National Institutes of Health (the "NIH") projects that by 2030, at least 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 2022 calendar year, which was published in June 2022 by Orthoworld Inc., (the "2022 Orthoworld Report"), worldwide sales of joint replacement products, including replacements for knees, hips, shoulders, elbows, wrists, ankles and digits outside of trauma, exceeded $17 billion in 2021 and are expected to grow to approximately $22 billion by the end of 2023.

The 2022 Orthoworld Report estimated that worldwide sales of knee replacement products totaled approximately $8 billion in 2021, and the United States represented approximately 65% of total estimated worldwide sales of such products.

According to the 2022 Orthoworld Report, worldwide sales of hip replacement products in 2021 totaled approximately $7 billion, and the United States represented approximately 59% of the total estimated worldwide hip replacement sales.

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 2022 Orthoworld Report, the worldwide extremities joint replacement market in 2021 was estimated at $2.2 billion.

The Conformis solution

With the rise of healthcare consumerism and the shift in procedures to ASCs, we believe we have a unique product offering and premium service program that can create an opportunity to disrupt the large, existing market for off-the-shelf orthopedic implants. Conformis now addresses multiple market segments within knee arthroplasty:

- the Identity Imprint™ knee system provides a data-informed high-quality knee implant system that provides a level of personalization through its PSI and proprietary algorithms for pre-surgical planning, but is only available in pre-designed standard sizes, all at a price comparable to customary standard off-the-shelf options; and

- the Image-to-Implant® Platinum Services℠ Program gives patients in the United States the opportunity to upgrade to a fully-personalized iTotal Identity™ knee system by paying an incremental deluxe services fee.

For our fully personalized knee products, we use our proprietary iFit Image-to-Implant technology platform to design and manufacture implants that are precisely sized and shaped to fit the unique three-dimensional curvatures of each patient's knee. Identity Imprint provides a level of personalization through its PSI and proprietary algorithms for pre-surgical planning that selects the implant size from 12 standard sizes that most closely meets the geometric and anatomic requirements of the patient’s knee based on the individual’s CT scan. For all our knee replacement solutions, we offer single-use patient-specific instrumentation, which we refer to as iJigs. We believe our proprietary iFit and iJig 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, ASC or other medical facility in advance of the scheduled arthroplasty procedure.

Key benefits of the iTotal and iTotal Identity Systems

We use our iFit technology platform to develop personalized joint replacement systems and single-use surgical instruments. We believe that our personalized joint replacement implants offer significant benefits to patients, surgeons, hospitals, ASCs and other medical facilities that are not afforded by competitive 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, thereby helping 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 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 solution 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 (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, ASC or other medical facility.** We believe that our implants 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 medical facility in a single, sterile, patient-labeled kit, eliminating the need for surgery centers to stock excess inventory for each surgical procedure. Unlike traditional 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 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 traditional 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 knee and hip implants can improve turnaround times with the potential for more procedures to be completed within the same amount of time and for hospitals or other medical facilities to generate additional revenue.

- *Shorter stays*. We believe that our personalized total joint replacements may shorten hospital or other medical facility stays. Our summary of the results of the 2017 AT Study indicates that a statistically significantly greater percentage of patients who underwent total knee replacement were discharged in fewer than three days following surgery (p=0.037) in the iTotal CR group (42%) than in the off-the-shelf group (30%). Our summary of a study published in Reconstructive Review in 2019, of 62 patients with either our iTotal CR or an off-the-shelf implant in a “Fast Track” protocol, also indicates that a significantly higher (p≤0.05) proportion of iTotal CR patients (66%) were discharged in less than 1 day when compared to off-the-shelf patients (30%).

- *Economic Savings*. We believe that our technology offers the potential of significant economic savings to hospitals or other medical facilities and payors. For example, the 2017 AT Study compared adverse events rates and cost of care for total knee arthroplasty patients treated with either personalized individually made implants or off-the-shelf implants. In that study, the total average real hospital costs between the personalized implant and off-the-shelf groups were nearly identical (customized implant $16,192 vs OTS $16,240), suggesting that patients with customized implants received improved hospital outcomes at no additional cost to the hospital. However, risk-adjusted per patient total cost of care showed a net savings of $914 per patient for the customized implant group for bundle of care, including the preoperative computed tomography scan, total knee arthroplasty hospitalization, and discharge disposition. Follow-up care costs demonstrated a savings of $1,313 per patient. Additionally, a retrospective study that we funded reviewed over 4,000 Medicare patients who had undergone total knee replacement, was published in the peer-reviewed journal *Orthopaedic Proceedings* in October 2018, indicated that the cost of care over a 12-month total episode of care was, on average, $1,697 lower for patients who received our personalized implants compared to patients who received off-the-shelf total knee implants. An abstract presented at the Orthopaedic Research Society 2021 Meeting demonstrated that Conformis iTotal, when compared to two competitive off-the-shelf implants, showed lower direct costs by more than $1,000 versus each off the shelf comparator knee.

- *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

To capitalize on the shift of elective total joint procedures from hospitals to outpatient facilities and ASCs and to address changing demands of the U.S. marketplace, we have evolved our portfolio and business model to seek to capture greater market share. Key elements of our strategy are to:

- ***Increase adoption of Identity Imprint™.*** In August 2021, the first procedure was performed using the Identity Imprint knee replacement system. Identity Imprint, available in both CR and PS implants, provides a data-informed high-quality knee implant system that provides a level of personalization through its PSI and proprietary algorithms for pre-surgical planning that selects the implant size from 12 standard sizes that most closely meets the geometric and anatomic requirements of the patient’s knee based on the individual’s CT scan. Identity Imprint is offered in a variety of standard sizes and was designed based on our extensive library of individual CT scans. Identity Imprint uses Conformis’ iJig technology and sterile Surgery-in-a-Box delivery system, which provides hospitals and ASCs with greater procedural efficiency and improved sterilization cost savings over comparable systems. Identity Imprint retains many of the benefits of our personalized knee products while reducing the delivery lead time and offering more intra-operative flexibility through standard poly insert options.

- ***Offer patients greater choice through the introduction of Image-to-Implant® Platinum Services℠ Program.*** The Image-to-Implant® Platinum Services℠ Program is our new U.S. deluxe services program through which medical facilities and patients can obtain a fully personalized iTotal Identity knee system.

  Both Medicare and most commercial payors permit patients to pay out-of-pocket for non-covered, deluxe services. Just as patients can pay extra for a private hospital bed or for a premium intraocular lens, our Image-to-Implant® Platinum Services℠ Program brings a first-of-its-kind premium pricing structure to orthopedics. We believe that the Image-to-Implant® Platinum Services℠ Program offers the following advantages:

  - there is no upfront investment or cost to the provider to enroll in this services upgrade program;
  - surgeons can offer personalization to patients as a shared clinical decision;
  - medical facilities can choose to charge patients an out-of-pocket fee for the Image-to-Implant® Platinum Services℠ Program that may include an incremental margin above their cost;
  - as part of the services upgrade, we provide patients a five-year limited warranty from the date of index surgery, underscoring our commitment to both manufacturing quality and superior clinical outcomes.

  The market research that was performed indicated that approximately one third of primary knee arthroplasty patients would be willing to pay an out-of-pocket premium for a personalized knee implant.

- ***Adapt our sales & marketing approach to address the business needs of ASCs.*** Traditionally, device companies have focused their marketing efforts primarily on surgeons. However, with the shift in orthopedic procedures to the outpatient setting, supply chain leaders and facility administrators now have a wider scope of influence and are looking for partners that can provide effective solutions to support their business operations. In addition, many surgeons are owners of ASCs, resulting in a heightened awareness of the economics of their device selections. In response to this changing market, we have adapted our sales approach and marketing messages to clearly communicate our unique value proposition with our innovative product offering, differentiated deluxe services program, and unique delivery model. In addition, we have deployed focused resources to engage ASCs at the local level, thus creating more opportunities to advance our product and service offering within this segment.

- ***Broaden our hip portfolio by launching additional complementary implant systems.*** On November 29, 2022, we announced that the first procedure with our new Actera™ Hip System has been performed. The system, designed for hip reconstruction, uses the cutting-edge tri-taper stem design, and features a range of sizes and angles derived from our data analytics. This cementless hip stem component features a proximally coated titanium spray with a hydroxyapatite layer to encourage initial and long-term fixation. We believe that the system's tri-taper stem design will enable surgeons to treat a broader range of patient anatomies and the shorter length options offer easier access to the femur while maintaining the fixation and integrity required for long term success of the implant. For the initial limited launch, the Actera™ Hip System will feature a range of standard sizes in both stem and cup components. We plan to launch future Actera™ line extensions that will offer additional personalization options for surgeons to choose what best fits their patients, even for complex anatomies.

- ***Expand our manufacturing processes to support the requirements of the new product offering.*** With the commercial introduction of Identity Imprint, we are expanding our manufacturing operations to support the business requirements that are associated with producing and delivering standard sized implants, while maintaining our unique Surgery-in-a-Box delivery model. In the short term, the expansion of our product portfolio has added complexity to the computer-aided design ("CAD" or "CAD designs") process, the management of our supply chain, and warehouse logistics. Over the longer term, as we continue to add capabilities across our operations, we will be better positioned to address the unique product demands and field logistics of the marketplace, which in turn will provide us with an important competitive advantage.

- ***Enhance our patent portfolio and continue to exploit our patent position.*** As of January 31, 2023, we own or exclusively in-license a total of approximately 241 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. Some of our products are standard products and others are personalized through proprietary software and services to fit individual patients. Historically we have been a personalized knee implant only manufacturer. However, with the introduction of our Identity Imprint platform we offer a total knee replacement system that is available in a range of standard sizes. Surgeons use our family of 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 FDC. We also have received CE Certificates of Conformity allowing us to affix the CE Mark to all mentioned products in Europe and applicable geographies for our legacy devices including iUni, iDuo, iTotal CR and iTotal PS. We are currently working on obtaining CE Certification under the new EU Medical Device Regulations (MDR) for our newest product offerings. We typically deliver our knee replacement implants and iJigs, together with our iView pre-surgical planning tool, to the hospital or other medical facility in pre-sterilized packaging in advance of the scheduled arthroplasty procedure.

Hip replacement products

We offer a line of primary hip replacement implants, including stems, heads, liners and acetabular cups. Some of our hip products are standard products and others are personalized through proprietary software and services to fit individual patients. We typically deliver our hip replacement implants together with iJigs, and with our iView pre-surgical planning tool to the hospital or other medical facility in pre-sterilized packaging in advance of the scheduled arthroplasty procedure. However, our hip system standard components may also be used without iJigs or an iView. Currently our hip replacement products are only available in the USA.

Conformis Hip Portfolio

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 two Conformis Hip Systems will provide clear synergies with our existing line of 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. Surgeons who understand the importance of personalization for total knee replacements will also be highly likely to embrace true personalization for hips. 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 combined Conformis Hip portfolio complements our existing product line and will allow us to expand our customer base, sales force and distribution channels.

Cordera Hip System

In addition to the patient-specific Conformis 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. 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.

Actera Hip System

To expand the sub-categories we compete in, we received FDA 510(k) clearance in September 2022 for the initial standard version of the Actera Hip System. We are seeking FDA 510(k) clearance for an expansion to the Actera™ Hip System which will incorporate a personalized surgical plan and patient specific instruments in 2023. The Actera Hip System, is an uncemented, primary total hip replacement composed of femoral and acetabular components. The stems are offered in a range of sizes and come in two standard neck angles and two standard neck lengths. The sizes and neck lengths were determined by using our CT database of pre-planned cases with previous hip systems. The design of the stem is conducive to direct anterior approach which is one of the faster growing segments of the hip market. Combined with our existing head and acetabular cup line, we believe that we can offer a competitive standard off-the-shelf system.

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 and standard implants to the patient. We believe that providing our iJigs with our implants enables a more accurate, reproducible and simplified surgical procedure by reducing the number of steps and increasing the precision of the alignment.

In a traditional off-the-shelf procedure, the surgeon must have a large number of reusable instruments available because the surgeon does not know in advance the appropriate implant size and 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 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 a traditional 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 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.

Human Capital Resources

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.

Employees

As of January 31, 2023, we had 295 full-time employees, 23 of whom were engaged in sales and marketing, 29 in research and development, 180 in manufacturing and service, 31 in regulatory, clinical affairs and quality activities and 32 in general administrative and accounting activities. None of our employees are covered by a collective bargaining agreement. We consider our relationships with our employees to be good.

Talent Development

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.

Diversity and Inclusion
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.

Competitive Compensation and Benefits
We believe in offering our valuable workforce a comprehensive benefits package with rich plan designs and competitive premiums. Some of our offerings include paid time-off with tenure based accrual, paid volunteer time-off, 401(k) plan with company match, medical insurance, dental insurance, vision insurance, and annual on-site flu shots, eye exams, and dental exams.

Safety and COVID-19
We take the health and safety of our employees seriously. With the spread of COVID-19 we must remain vigilant in mitigating the effects of the outbreak. In order to be safe and to maintain operations, we have developed and implemented a comprehensive COVID-19 Safety Policy throughout all of our facilities and operations. Our policy includes guidelines for face coverings, cleaning & disinfecting, general hygiene, and the monitoring of cases in our workforce.

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, 2023, there have been more than [35] 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, Brazil, Australia, the United Arab Emirates, the Sultanate of Oman, Italy, 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 ASCs, and patients. As part of our new business model, in the US, we also offer full-personalization as a premium service and additional revenue stream. 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 in the US and abroad.

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 and delivery model 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 traditional model with the off-the-shelf implant manufacturers. This potentially will allow our sales representatives to spend more time on new customer growth opportunities.

Our surgeon users appreciate the clinical and economic benefits, including increased patient satisfaction, operating room efficiencies and lower adverse event rates, that our products have been demonstrated to offer. In addition, we believe surgeons will increase their interest in the additional patient surgical planning information and improved surgical efficiencies provided by our Conformis Hip Systems. We believe hospitals and other medical

facilities, including ASCs, will increase their focus and attention on the economic benefits that our products offer, 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, better long-term satisfaction, and will be attracted to our personalized approach. To engage them, we employ direct-to-consumer marketing, primarily through patient testimonials, social media, search engine marketing, referral campaigns, online, radio and television news reports.

In the United States, we focus our commercial efforts by targeting surgeons and facilities that have the most regional favorable trends such as procedure volumes, surgeon density, and other factors. Part of our commercial strategy is offering the full personalization as a premium upgrade service that is paid by the patient out of pocket. We believe facilities will be interested in this service as a way to increase patient choices and drive increased surgical economics and patient demand. To support these efforts, we offer a comprehensive menu of marketing opportunities to partner with these facilities to increase patient and referral awareness in these markets. Globally, we look for markets with a high volume of total knee replacements, favorable reimbursement characteristics and an historical openness to advanced technologies.

Research and development

Our internal research and development efforts are focused on continued innovation to develop 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 29 full-time research and development employees has extensive experience in biomechanical engineering, manufacturing engineering and software engineering and development. A portion of our research and development activities involves the development of proprietary algorithms and computer software that underpins our entire technology platform. For the years ended December 31, 2022, and 2021, company-sponsored research and development expense was $15.3 million, and $14.8 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, CAD designs on a per-patient basis either in-house and/or through a third party in India. We use the result of these CAD 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, at the end of 2020, we opened an office in India with a CAD team. We manufacture all of our PSI, including 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:

- develop new versions of our software used in the design of our joint replacement implants, which we believe will reduce costs associated with the design process;
- continue to increase the amount of CAD design activities performed at our India facility to reduce the manufacturing costs associated with the CAD portion of our 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 PSI. 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 PSI. 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 that they are compliant with the FDA's QSR. Our quality management system is regularly audited by the Notified Body BSI Group The Netherlands B.V. (“BSI”) against the International Standards Organization (“ISO”) Standard 13485 and the quality system requirements of the EU MDD. Compliance with the ISO 13485 Standard permits us to benefit from a presumption of conformity with quality system requirements laid down in the EU MDD and, in the future, the MDR, as applicable. 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 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 implants and iJigs.

Patent rights

As of January 31, 2023, we owned or exclusively in-licensed 195 issued patents around the world, including 60 patents issued in the United States and 135 foreign patents.

- The patents that we own relating primarily to our personalized joint replacement implants are expected to expire between 2023 and 2035.
- The patents that we own relating primarily to our patient-specific instrumentation are expected to expire between 2023 and 2036.
- The patents that we own relating primarily to our iFit technology platform are expected to expire between 2023 and 2036.

As of January 31, 2023, we owned or exclusively in-licensed 46 patent applications, including 15 patent applications pending in the United States and 31 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, if patents issue on these applications, they would be expected to expire between 2023 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;
    - advancements in implant design applicable to both personalized and non-personalized systems;
    - 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 PSI and associated implant components in the knee, including MicroPort's Prophecy PSI 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 Technology, Inc. ("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 PSI 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 ("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, 2021, we had successfully completed the third of three milestones with Stryker and received $11.0 million, for a total aggregate received of $16.0 million for achievement of these milestones. Under the long-term Distribution Agreement, we supply patient-specific instrumentation to Stryker.

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 (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 PSI 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.

License agreement with Paragon 28

On April 8, 2021, the Company entered into a license agreement (the “License Agreement”) with Paragon 28, Inc. ("Paragon 28"), granting Paragon 28 a non-exclusive license under a subset of the Company's U.S. patents for the use of PSI with off-the-shelf implants in Paragon 28’s APEX 3D Total Ankle Replacement System. In consideration for the license, the Company received $0.5 million upon execution of the License Agreement, another $0.5 million in October 2021, and may receive an additional $0.5 million from Paragon 28 before April 8, 2022. In connection with this License Agreement, the Company recognized revenue of $1.0 million during the quarter ended June 30, 2021. The remaining $0.5 million was recognized as revenue during the quarter ended March 31, 2022.

License and settlement agreement with Stryker and Wright Medical

On June 30, 2021 the Company entered into a settlement and license agreement (the “Settlement and License Agreement”) with Stryker, Wright Medical, and Tornier, Inc. (“Tornier” and, collectively with Stryker and Wright Medical, the "Stryker Parties"), pursuant to which the parties 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 the Stryker Parties, the Stryker Parties were required to make a one-time payment to the Company of $15.0 million no later than October 15, 2021. The agreement provided for the grant of the licenses, covenants-not-to-sue, releases, and other 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 the Stryker Parties is not separately identifiable from other promises in the agreement. As a result, the Company accounts for the promises in the Settlement and License Agreement as a single performance obligation. The Stryker Parties 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 Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 606"). In connection with the Settlement and License Agreement, the Company recognized revenue of $15.0 million during the quarter ended June 30, 2021 and payment in the same amount was received from the Stryker Parties on October 15, 2021. See “Note H—Commitments and Contingencies, Legal proceedings” for further discussion of the Stryker Parties settlement.

Settlement and licensing agreement with Medacta

On November 8, 2022, we entered into a non-exclusive, fully paid up, worldwide license agreement with Medacta USA, Inc., Medacta International SA, and Medacta Germany GmbH (collectively, "Medacta"). Under the terms of this license agreement, we granted a perpetual, irrevocable, non-exclusive license to Medacta to use patient-specific instrument technology covered by our patents and patent applications with off-the-shelf implants for the knee and shoulder. This license does not extend to patient-specific implants. This license agreement provided for a single lump-sum payment by Medacta to us upon entering into the license agreement, which has been paid. See “Note H—Commitments and Contingencies, Legal proceedings” for further discussion of the Medacta settlement.

Trademarks

As of January 31, 2023, we have filed 142 trademark registrations in the United States and in other major markets worldwide, including the following marks: Conformis, iFit, iTotal, iDuo, and iUni. We have 1 trademark application pending worldwide.

Competition

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

We compete with several large, well-known companies that dominate the market for orthopedic products, principally Zimmer Biomet, Stryker, DePuy Synthes, Inc., and Smith & Nephew, Inc. 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. 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 small to mid-sized companies that are developing and marketing competitive joint replacement products, as well as companies exploring alternatives to joint replacement such as biologic injections and cartilage repair systems.

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

- the expertise and clinical history of designing, manufacturing, delivering and implanting patient specific instrumentation and implants;
- the breadth and depth of our clinical data-base that allows us to use real world three- dimensional data to design and introduce innovative products that are differentiated from competitors' offerings and represent an improvement over currently available products through better anatomic fit and function;
- Our software artificial intelligence, AI, and data-driven decision making by using real patient data to create an accurate pre-operative surgical plan that is tailored to each patient;
- the ability to deliver products in a sterile and efficient manner that helps improve the cost effectiveness of the procedure and resource optimization;
- 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; and
- the reach and depth of each competitor's distribution capabilities.

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 driven by the personalized in the high single digits 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 pursuant to the FDCA and the regulations promulgated under 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 the 510(k) premarket notification pathway or de novo request pathway, or has been approved by the FDA pursuant to a premarket approval ("PMA") application or Humanitarian Device Exemption ("HDE"). The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies according to several factors, including 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. Specifically in regard to low-to-moderate risk devices that are placed in Class III by default because a legally marketed predicate device cannot be found, sponsors may file a de novo request that, if granted, will reclassify the device either into Class I or Class II and will allow the sponsor to market the device in the US. 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 de novo request, 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, validaton 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 Regulation (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices("the EU MDR") sets out the basic regulatory framework currently applicable to medical devices in the EEA. The EU MDR became applicable on May 26, 2021, repealing the prior Council Directive 93/42/EEC, the EU MDD, which had been regulating medical devices in the EEA for the past over 20 years. This represented a major change in the regulatory landscape of medical devices in the EEA. The EU MDR sets out certain transitional provisions that allow for medical devices covered by the repealed EU MDD (called "legacy devices") to still be marketed in the EEA for a certain period of time. Unlike directives, which must be implemented into the national laws of the individual EEA Member States, the EU MDR is directly applicable, i.e., without the need for adoption of national implement laws in the individual EEA countries. This aims to eliminate the differences in the regulation of medical devices among EEA countries that existed under the EU MDD. The EU 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 EU MDR aims, among other things, to:

- 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; and
- 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.

In the EEA, our medical devices must comply with the General Safety and Performance Requirements in Annex I to the EU MDR (for legacy devices, this corresponds to the Essential Requirements of Annex I to the EU MDD). Compliance with these General Safety and Performance 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 General Safety and Performance Requirements of the EU MDR 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 devices that have no measuring function, are not sterile and are not reusable surgical instruments), in relation to which the manufacturer can issue an EU Declaration of Conformity based on a self-assessment of the conformity of its products with the General Safety and Performance 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 management 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 General Safety and Performance 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 EU Declaration of Conformity.

As a general rule, confirmation of conformity of medical devices with the General Safety and Performance Requirements under the normal conditions of intended use of the devices, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk-ratio, shall be based on clinical data providing sufficient clinical evidence, including where applicable relevant post-market data. The EU MDR defines "clinical evidence" as "clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer." In light of this definition, manufacturers of medical devices are required to have sufficient clinical data and clinical evaluation results related to their devices.

Manufacturers are required to specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant General Safety and Performance Requirements. This level of clinical evidence must be appropriate in view of the characteristics of the device and its intended purpose. For this purpose, Article 61 of the EU MDR requires manufacturers to plan, conduct and implement a clinical evaluation which is defined as "a systematic and planned process to continuously generate, collect, analyze and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer." The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report.

The conduct of clinical investigations is mandatory for implantable and Class III medical devices under the EU MDR. These clinical investigations aim to generate sufficient clinical evidence to support a CE marking application with the relevant Notified Body. Prior to carrying out a clinical evaluation or investigation, manufacturers of Class III devices and certain Class IIb devices may consult an expert panel to review the intended clinical development strategy and proposals for clinical investigations. 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.

The EU MDR has increased the scrutiny and assessment rules for high-risk medical devices, such as Class III medical devices. This has notably been translated through the following main additional requirements for Class III medical devices:

- Conformity Assessment based on Quality Management (Annex IX) requires a full assessment of the quality management system and the assessment of the Technical Documentation for each product;
- Additional scrutiny procedure for Class III implantable medical devices pursuant to Article 54 of the EU MDR: Clinical Evaluation Consultation Procedure where in the course of the conformity assessment the Notified Body seeks an opinion from the expert panel designated by the European Commission;
- Drawing up a Summary of Safety and Clinical Performance (SSCP) which must be validated by the Notified Body, made available through EUDAMED database and updated annually;
- Mandatory conduct of clinical investigations as mentioned above;
- Annual updating of the Post-Market Clinical Follow-up (PMCF) Report; and
- Submission of the Periodic Safety Update Report (PSUR) to the Notified Body via EUDAMED for the Notified Body's review.

The EU MDR therefore imposes increased compliance obligations for us to access and then remain on the EEA market.

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 EEA. 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 Group The Netherlands B.V. (originally BSI UK).

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 issued under the EU MDD are valid through December 2, 2022 for our iUni product, May 26, 2024 for our iDuo product, May 26, 2024 for our iTotal PS product and May 26, 2024 for our iTotal CR. At the end of each period of validity, we will be required to apply to the Notified Body for a new CE Certificate of Conformity issued under the EU MDR.

CE Certificates of Conformity issued under the EU MDR are valid for the period they indicate, with a maximum period of five years. The manufacturers may apply for the validity of the Certificates to be extended for further periods, each not exceeding five years, based on a re-assessment of the manufacturers and devices compliance with applicable requirements. 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 General Safety and Performance Requirements or the devices' intended purpose. The Notified Body will then assess the changes and verify whether they affect the products' conformity with the General Safety and Performance 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 General Safety and Performance Requirements. If it is not, we may not be able to continue to market and sell the product in the EEA.

We and the Notified Body who will oversee compliance with the new EU MDR face uncertainties as the EU 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.

The EU MDR introduced substantial changes to the obligations applicable to medical device manufacturers and Notified Bodies in the EEA. As a result, there are less Notified Bodies available to conduct conformity

assessments under the EU MDR and the number of certification requests has increased substantially. The EU MDR is new and a number of guidance documents are still not available to guide manufacturers and Notified Bodies. As a result, the time needed to find a Notified Body available and go through a conformity assessment procedure has substantially increased. For these reasons, the new EU MDR may create uncertainties for the CE marking of our devices and cause delays to access the market.

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 EU 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 believe that we are compliant with the applicable requirements of the EU MDR.

UK and Brexit

The United Kingdom withdrew from the EU on January 31, 2020 (the withdrawal is commonly referred to as “Brexit”). 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, but does not specifically address medical devices.

After the UK’s withdrawal from the EU, Great Britain (England, Scotland and Wales) is treated as a third country. Northern Ireland continues, with regard to EU regulations, 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. The route to market and the UKCA marking requirements are based on the requirements of the EU MDD. Northern Ireland will 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.

Since January 1, 2021, the Medical Devices (EU Exit) Regulations 2020 introduced a number of changes to how medical devices are placed on the Great Britain’s market.

The CE marking will continue to be recognized 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 (MDSS-UK RP Ltd.) and the EU (MDSS GmbH). 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 Group The Netherlands B.V. 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. Article 7 of the EU MDR prohibits the use of text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by (i) ascribing functions and properties to the device which the device does not have; (ii) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have; (iii) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose; and (iv) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

The advertising and promotion of our products in the EEA is also subject to EEA countries’ national laws implementing Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices. National legislation of individual EEA countries governing the advertising and promotion of medical devices also applies. 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 serious incidents involving devices they manufacture to the Competent Authority in whose EEA jurisdiction the incident occurred and to the MHRA in the UK. Under the EU MDR, a serious incident is defined as any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat. Manufacturers must also notify competent authorities of any field safety corrective actions (including those undertaken in a third country in relation to a device which is also made available on the EEA market, if the reason for the field safety corrective action is not limited to the device made available in the third country).

Manufacturers are required to take field safety corrective actions, or FSCAs, to prevent or reduce a risk of a serious incident 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. To obtain reimbursement or pricing approval, some of these EEA countries may require the completion of clinical studies that compare the cost-effectiveness of a particular device candidate to currently available therapies. Other EEA countries allow companies to fix their own prices for medical devices, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new devices. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

In recent years, a number of EEA countries have introduced so-called health technology assessments (HTA). HTA measures the added value of a new health technology, in our case a medical device, compared to existing ones. HTA's assessment include cost implications for the patient and its impact on the organization of healthcare systems in the administration of treatment. An EU Regulation on HTA entered into force in January 2022 and will be applied three years later (January 2025). It offers the possibility for EEA countries' HTA bodies to conduct Joint Clinical Assessments of new high-risk medical devices.

In January 2021, the rate of reimbursement for surgical procedures using our products in Germany was changed. Beginning January 1, 2021, the reimbursement for surgical procedures using our iTotal CR and iTotal PS products increased by approximately 0.6%, while the reimbursement for surgical procedures using our iUni and iDuo products increased by approximately 8%. For the years ended December 31, 2022 and 2021, sales in Germany represented 6% and 9% of our total product sales, respectively. 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 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. We have implemented pre-approval techniques in order to seek prior approval for procedures.

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 receive 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. Applicable manufacturers also are 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.

In the EEA, interactions between medical devices companies and physicians are also governed by strict laws, such as national anti-bribery laws of EEA countries, national Sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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 EEA that, among other things, unifies data protection regulation within the EEA and governs the export of certain personal data and health information of data subjects in the EEA. 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 or prevent clearance of a 510(k), necessitate the withdrawal of a pending 510(k) notice, or cause a filed 510(k) to be placed on Refuse to Accept hold prior to FDA's initiation of its substantive review.

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, is directly applicable in each EEA country. 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). The GDPR also imposes 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 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. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EEA countries may result in fines of up to €20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. The obligations under the GDPR may therefore be onerous and adversely affect our business, financial condition, results of operations and prospects.

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 and distributors managed by that respective country. 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.

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 Securities Exchange Act of 1934, as amended (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. This section contains forward-looking statements, and in considering these statements, you should refer to the qualifications and limitations on our forward-looking statements that are described in "Forward-Looking Statements" included in Part I of this Annual Report on Form 10-K. 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 $50 million for the year ended December 31, 2022, and $2 million for the year ended December 31, 2021. As of December 31, 2022, we had an accumulated deficit of $581 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.

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

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

- our sales and marketing efforts, including the expanded advertising of our Platinum Services℠ Program;
- expansion of our manufacturing capacity;
- funding research and development activities related to new and existing products, including our porous-coated technology for the Imprint system and Actera™ line extensions; and
- enforcing our intellectual property rights and pursuing our claims against Aetna.

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

We anticipate that our principal sources of funds in the future will be revenue generated from the sale of our products, potential future capital raises through the issuance of equity or other securities, available sales of shares under the Sales Agreement, potential debt financings and revenue that we may generate in connection with licensing our intellectual property. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted. The terms of these future equity or debt securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders or involve negative covenants that restrict our ability to take specific actions, such as incurring additional debt or making capital expenditures. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, and we may even be required to scale back our operations.

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

On November 22, 2021, we entered into a Credit and Security Agreement (the "New Credit Agreement") with MidCap Financial Trust ("MidCap"), as agent, and certain lender parties thereto. The New Credit Agreement provides for a five-year, $21 million secured term loan facility (the "Term Facility"). The New Credit Agreement refinanced and replaced our prior 2019 secured credit facility with Innovatus (the "2019 Secured Loan Agreement"). We used the amounts drawn under the New Credit Agreement to repay all outstanding obligations under the 2019 Secured Loan Agreement, which 2019 Secured Credit Loan Agreement has been terminated.

The New Credit Agreement contains customary affirmative and negative covenants, including limitations on our ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, pay subordinated indebtedness and enter into affiliate transactions. In addition, the New Credit Agreement contains a minimum liquidity covenant

requiring us to maintain unrestricted cash and cash equivalents in excess of $4.0 million. The New Credit Agreement also includes events of default customary for facilities of this type and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Term Facility may be accelerated. For further information regarding the New Credit Agreement with MidCap Financial Services, 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 New Credit Facility, 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, 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

With the transition to Identity Imprint™ as our primary knee system in the U.S. and with the introduction of our new Image-to-Implant® Platinum Services℠ Program, new operational and regulatory risks may arise

We have recently evolved our product portfolio for knee arthroplasty, launching our new Identity Imprint™ knee system (“Identity Imprint”), which is now our primary knee system in the U.S. Identity Imprint offers a high-quality knee implant system that provides a level of personalization through its patient-specific instruments and proprietary algorithms for pre-surgical planning. Identity Imprint incorporates standard sizes developed using our clinical database of information, with implant sizing optimized for each patient using advanced algorithms. Identity Imprint maintains our “surgery-in-a-box” delivery model that we believe optimizes its efficiency for use in sites such as ambulatory surgery centers, as the product uses a minimal shelf footprint and is compatible with a reusable instrument set. Identity Imprint is designed to meet the standard of care for all patient procedures, and we believe it represents a compelling value proposition for customers.

With the Identity Imprint transition, we now offer healthcare facilities and patients the ability to obtain a fully personalized iTotal Identity knee system through a deluxe services upgrade. We are marketing this program as our Platinum Services℠ Program (PSP). Under this program, medical facilities and surgeons enrolled in the program will have the option to charge an out-of-pocket fee to patients who request the Platinum Service Program. This fee may include an incremental margin above the cost we charge to the medical facility and/or surgeon. As part of the upgrade, we provide patients a five-year limited warranty from the date of index surgery. It is important to note that the ultimate financial arrangement between the medical facilities, surgeons and their patients to pay for the PSP is between them and does not involve Conformis.

While we believe that our transition to Identity Imprint and PSP creates the potential for significant product and market share growth, this transition exposes us to various risks. For example, some of our existing customers have chosen not to offer the services to obtain our fully personalized iTotal Identity product given it requires an out-of-pocket patient pay upgrade and some have chosen not to order Identity Imprint given it is not a fully personalized knee system. Additionally, to support our Identity Imprint product offering, we are implementing a "build-to-stock" manufacturing model alongside our "just-in-time" model, which creates an increase in complexity and requires different talent and experience to implement and manage the manufacturing dynamics and supply chain requirements.

In addition, our PSP model is predicated on the upgraded services constituting “deluxe” features under reimbursement rules promulgated by CMS, which allow providers to charge patients for services that provide added convenience or patient comfort and that are not medically necessary, while still receiving the standard reimbursement rate from Medicare or Medicaid. It is possible that CMS or insurers could disagree that the PSP provides deluxe services that would permit patients to request and pay out-of-pocket for the services under the program, or conclude that PSP otherwise violates applicable rules and regulations. Any such disagreement or

allegation of noncompliance, if it were to occur, could materially disrupt our ability to implement the program, or expose us to other legal liabilities.

Any of these execution and/or regulatory risks could cause us to fail to successfully implement our plan to increase product sales and market penetration through Identity Imprint and the Platinum Service Program, which could lead to a material adverse effect on our business, operations and financial condition.

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 and hip replacement products, and we expect that sales of these products and our new PSP 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 and services, 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 and services, including the size of the addressable markets for these products, our failure to compel surgeons to adopt our products, competitive factors and other considerations described in these risk factors, could adversely affect our business, financial condition and operating results.

We work to 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 could adversely affect our financial condition and operating results.

In addition, as part of our commercial strategy, we are targeting ASCs and outpatient facilities. These facilities have unique needs and may prefer to partner with larger, more established companies that offer a broader array of products and services. The lack of adoption from this customer segment 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, (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.

With the implementation of the EU MDR, new regulatory burden has been placed on the manufacturer for products intended to be distributed within the EU.

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. 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 commercial relations with, in some cases over decades, orthopedic surgeons, hospitals, ASCs and other medical facilities, third-party payors and independent sales representatives and distributors;
- recognized products that are more widely accepted by, a greater number of orthopedic surgeons, hospitals and other medical facilities and third-party payors;
- more complete product lines for knee, hip or other joint replacements;
- a robotic surgical offering or platform;
- a cementless total knee arthroplasty offering;
- 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 discredit or copy Image-to-Implant® Platinum Services℠ Program, which would have the effect of reducing the market potential of our current offering.

In order to become profitable, we will need to scale our business model considerably through increased profitable sales.

In order to become profitable and increase our gross margin, we will need to significantly increase sales of our existing products and services, expand our manufacturing capabilities, and successfully develop, launch, and commercially scale future products 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 through the launch of Identity Imprint™ and our Image-to-Implant® Platinum Services℠ Program;
- 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;
- increasing the proportion of our CAD design activities that is performed in-house at our India facility;
- 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;
- improve the efficiency of our internal manufacturing processes;
- leverage existing manufacturing overhead costs over increased production volume.

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 and services program 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 may not widely adopt our products unless they determine, based on professional experience, economic evidence, clinical data and published peer-reviewed journal articles, that our products, services, and techniques to implant our knee and hip systems 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 designed 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 Cordera and Actera hip replacement products. 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 or certification for the sale of our products outside the United States. 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 our Identity Imprint™, iTotal Identity™, and Actera™ Hip System is less than we expect or we incur delays in introducing new products, 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 (and in Aetna’s case, we have commenced litigation against them), 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 member hospitals and other medical facilities. If we do not have pricing agreements with group purchasing organizations, their member 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 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.

Technology changes and surgeon adaptation are uncertain and we may not accurately predict the changing demands by our customers. Robotic and cementless arthroplasty procedures are growing and we currently do not have these offerings. Augmented reality and advanced tracking technologies are in various stages of development and deployment. Our ability to maintain and/or grow surgeon users could be negatively impacted if we are not able to offer these or any other new options demanded by surgeons.

Robotic TKA uses software (e.g., pre-operative CT or intraoperative tibia and femur mapping) to convert anatomical images of the patient's knee into three-dimension images. These images aid the performing surgeon in bone cutting and implant placement to minimize injury to soft tissue and bone. Additionally, in conventional TKA, implant components are secured in the patient's joint using bone cement. In cementless TKA, implant components are press fit into place to achieve "biological fixation," permitting the bone to grow into the implant.

Although we are continually engaged in product development, we do not currently have a robotic or cementless TKA option. As some of our competitors have developed robotic and cementless TKA options, they may gain a competitive advantage over our current products and technologies.

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 COVID-19 pandemic and the response to it reduced demand for our products, and as a result we reduced our operations and production capacity, and these circumstances had a significant negative affect on our revenue.

Our business was 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.

The pandemic also negatively affected our manufacturing and delivery timelines, in part because of additional employee turnover at our manufacturing facility, and the difficulty of finding, hiring and training new employees on a timely basis. For example, the stringent manufacturing protocols that we follow require new manufacturing employees to receive substantial training to reach proper levels of work proficiency, and thus increased employee turnover during the pandemic negatively affected our ability to maintain the same pace of manufacturing. In addition, employee turnover and tight labor conditions in the third-party shipping sector contributed during the pandemic to an increased number of delays in the timing of products we manufacture reaching surgeon recipients. Collectively, these pandemic-related factors made it more difficult for us to satisfy consumer demand for our products. To the extent these pandemic-related labor constraints continue, it could adversely affect our sales and profitability for the duration of time that such conditions continue.

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 entities such as Notified Bodies for the EEA.

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, 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 2017 and 2018, we continued transitioning our CAD labor force through a third-party CAD-designer in India and, in the fourth quarter of 2020, we established a new Conformis entity in India, Conformis India LLP, and transitioned 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 rely on third-party services for ethylene oxide ("EO") sterilization of some of our products. In the United States, several regulators, including the EPA, FDA, and agencies at the state and local level, play a role in regulating the use of EO sterilization. In 2016, the EPA changed the cancer risk basis for EO and determined that EO is carcinogenic to humans. Recent announcements of the temporary or permanent closure of EO sterilization facilities operated by third parties has limited the capacity of EO services. Given the nature of our just-in-time model, an impact on the timely availability of EO services could impact the cost and availability of our product.

While we have alternate modalities of sterilization, for some of our products EO sterilization may be the only regulatory approved method of sterilization available to us that effectively sterilizes and does not damage the device during the sterilization process.

In the event of regulatory, legislative, or legal action that curtails or eliminates EO sterilization, we may be unable to provide our products in a timely manner.

Implementation of new or modified sterilization methods may require additional validation of revised or new manufacturing process, FDA clearance, that could create delays and/or could impact our ability to grow our business in the future.

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 our fully personalized products are individually made to fit an individual patient following their receipt of personalized services, 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 for our personalized products, 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.

Risks related to our Information Technology, Cybersecurity and Data Protection

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, the United Arab Emirates, the Sultanate of Oman, Italy, 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 our long-range business plan, and as a result, we may encounter difficulties in managing our operations.

In the first quarter of 2022 we announced the launch of our new Image-to-Implant Platinum Services℠ Program. This new program combined with our existing and future product portfolio are the basis for our 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 expiration of the term for rights granted to us under our patents with the earliest priority dates may provide opportunities for our competitors to offer products or technologies similar to our own. 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;
- non-renewal, suspension, or withdrawal of our CE Certificates of Conformity, which allow us to affix 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 request 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 several factors, including 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, which typically does not require clearance via a premarket notification, or Class 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. Assuming that there is no legally marketed predicate device available, 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 or de novo clearance, 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 de novo request clearances, 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) or de novo 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 legislation (the Medical Devices Directive or EU MDD and, from May 26, 2021, the Medical Device Regulation, or EU 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 certification from an independent Notified Body. 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 General Safety and Performance 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 incidents or incidents 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, non-renewal,suspension or withdrawal of CE Certificates of Conformity, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. The non-renewal, withdrawal, or suspension of 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, expanded on, 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.

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, or the EU MDR, entered into application on May 26, 2021. The EU MDR introduced 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 EU MDR repeals and replaces the EU MDD.

It is 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 EU MDR. The number of Notified Bodies that have been designated to conduct these assessments under the EU MDR is still relatively small when compared to that under the EU MDD. This is currently delaying conformity assessment procedures in the EEA.

The EU MDR imposes 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 EU MDR (and with the EU MDD for our legacy devices). The new requirements imposed on manufacturers

of medical devices by the EU 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". Great Britain (England, Scotland and Wales) is now treated as a third country. Northern Ireland continues, with regard to EU regulations, 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 EEA, 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 Requirements under and the EU 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. Compliance with harmonized standards in the EEA 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 EEA, 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.

BSI Group The Netherlands B.V., 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 ISO 13485 in all material respects and preforms periodic full recertification audits of our quality management system in order to confirm that we comply with the requirements of the EU 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 prevent or 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 EU MDR, a serious incident is defined as any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat. Manufacturers must also notify competent authorities of any field safety corrective actions (including those undertaken in a third country in relation to a device which is also made available on the EEA market, if the reason for the field safety corrective action is not limited to the device made available in the third country). 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, voluntary recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. 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 EU MDR, to the national laws of the individual EEA counties implementing the 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. 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.

The barrier-free trade of medical devices between the European Union and Switzerland under the Mutual Recognition Agreement (MRA) ceased to apply on May 26, 2021, which may adversely affect our financial results and our operations in Switzerland.

Switzerland is a European country, but it is not part of the European Union ("EU"). It is part of the European Free Trade Association ("EFTA"), together with the three countries that make up the European Economic Area ("EEA"). The EEA follows all EU product legislation automatically, but EFTA is not bound to that requirement. Trade with Switzerland is established via multiple mutual recognition agreements. There is a Mutual Recognition Agreement (MRA) covering medical devices in order to enable these devices to move freely between the EU and Swiss markets. However, the current MRA does not cover the EU MDR and, as a result, Switzerland is considered a third country for medical device trade purposes. All foreign manufacturers must, from May 26, 2021, adhere to the revised Swiss Medical Devices Ordinance and to the requirements for the import of medical devices, namely the designation of an importer and a Swiss authorized representative (for which certain transitional periods are in place). During a transition period, devices that comply with the EU MDD and were CE-marked according to EU MDD (legacy devices) may continue to be placed on the Swiss market, even after the entry into force of the revised Swiss Medical Devices Ordinance, provided that certain conditions are met.

The need for compliance with the revised Swiss Medical Devices Ordinance could adversely affect our sales in Switzerland, as well as our existing and future customers and future employees in Switzerland. The revised Swiss Medical Devices Ordinance could lead to legal uncertainty and divergences with the EU MDR and its implementation can affect our compliance efforts.

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

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription and use of our products and any other product candidates for which we obtain marketing clearance. Our 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 receive 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, and as of this year, to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives, 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 (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 receive 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. In November 2020, California voters approved the California Privacy Rights Act ("CPRA") ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency ("CPPA"). The amendments introduced by the CPRA go into effect on January 1, 2023, and new implementing regulations are expected to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and damages. 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 Federal Trade Commission ("FTC") also sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act ("FTC Act"). The FTC

expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

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 imposes penalties up to EUR 20 million or 4% of annual global revenue of a noncompliant company, whichever is greater. In addition, laws and regulations enacted in the United States, Europe, Asia and Latin America, including the new California Consumer Privacy Act, 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 will 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. The European Commission has adopted an Adequacy Decision concerning the level of data protection in the UK. Personal data may now flow freely from the EU to the UK, however, the European Commission may suspend the Adequacy Decision if it considers that the UK no longer provides for an adequate level of data protection. Enforcement by EU and UK regulators is active, and failure to comply with the GDPR or applicable Member State law may result in substantial fines.

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. The GDPR generally restricts the transfer of personal data from the EEA and Switzerland to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards allowing U.S. companies to import personal data from Europe had been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. However, the EU-U.S. Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union, or CJEU, in a case known colloquially as "Schrems II." Following this decision, the Swiss Federal Data Protection and Information Commissioner, or the FDPIC, announced that the Swiss-U.S. Privacy Shield does not provide adequate safeguards for the purposes of personal data transfers from Switzerland to the United States. While the FDPIC does not have authority to invalidate the Swiss-U.S. Privacy Shield regime, the FDPIC's announcement casts doubt on

the viability of the Swiss-U.S. Privacy Shield as a future compliance mechanism for Swiss-U.S. data transfers. The CJEU's decision in Schrems II also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal data transfers from Europe to the United States or other third countries that are not the subject of an adequacy decision of the European Commission.

While the CJEU upheld the adequacy of the Standard Contractual Clauses in principle in Schrems II, it made clear that reliance on those Clauses alone may not necessarily be sufficient in all circumstances. Use of the Standard Contractual Clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular regarding applicable surveillance laws and relevant rights of individuals with respect to the transferred data. In the context of any given transfer, where the legal regime applicable in the destination country may or does conflict with the intended operation of the Standard Contractual Clauses and/or applicable European law, the decision in Schrems II and subsequent draft guidance from the European Data Protection Board, or EDPB, would require the parties to that transfer to implement certain supplementary technical, organizational and/or contractual measures to rely on the Standard Contractual Clauses as a compliant "transfer mechanism." However, the draft guidance from the EDPB on such supplementary technical, organizational and/or contractual measures appears to conclude that no combination of such measures could be sufficient to allow effective reliance on the Standard Contractual Clauses in the context of transfers of personal data "in the clear" to recipients in countries where the power granted to public authorities to access the transferred data goes beyond that which is "necessary and proportionate in a democratic society" – which may, following the CJEU's conclusions in Schrems II on relevant powers of United States public authorities and commentary in that draft EDPB guidance, include the United States in certain circumstances (e.g., where Section 702 of the US Foreign Intelligence Surveillance Act applies). At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. The decision in Schrems II also affects transfers from the United Kingdom to the United States.

Furthermore, following the UK's exit from the EU, the UK became a third country to the EEA in terms of personal data transfers. The EC has adopted an Adequacy Decision concerning the level of personal data protection. However, personal data transfers from the EEA to the UK may nevertheless be at a greater risk than before because an Adequacy Decision may be suspended.

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

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.” On December 31, 2021, we received a notification letter from Nasdaq’s Listing Qualifications Staff notifying us that the closing bid price for our common stock had been below $1.00 for the previous 30 consecutive business days and that we therefore are not in compliance with the minimum bid price requirement for continued inclusion on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). We subsequently implemented a 1-for-25 reverse stock split, and regained compliance with these requirements.

However, there can be no assurance that the market price of our common stock will remain at the level required for continuing compliance with that requirement. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. Other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock and thus jeopardize our ability to meet or maintain the Nasdaq’s minimum bid price requirement.

Any future 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, 2022, we had federal net operating loss, or NOL, carryforwards of $470 million and state NOL carryforwards of $274 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 (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 3,238,095 shares of our common stock at a public offering price of $26.25 per share (adjusted for the 1-for-25 reverse stock split), 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 2023.

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 September 2027 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 2024 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*

For information regarding 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.

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

Certain Information Regarding the Trading of Our Common Stock

Our common stock currently trades under the symbol “CFMS” on the Nasdaq Capital Market. The following table sets forth the high and low sales price of our common stock as reported on the Nasdaq Capital Market, as applicable, for the periods indicated (retroactively restated on a pro forma basis for the 1-for-25 reverse stock split of our common stock that we consummated in November 2022):

	High	Low
Year ended December 31, 2021:		
First Quarter	$ 35.00	$ 16.56
Second Quarter	$ 33.50	$ 19.75
Third Quarter	$ 45.75	$ 25.50
Fourth Quarter	$ 33.00	$ 16.69
Year ended December 31, 2022:		
First Quarter	$ 20.68	$ 13.86
Second Quarter	$ 16.29	$ 6.88
Third Quarter	$ 9.25	$ 4.78
Fourth Quarter	$ 5.25	$ 1.25

Holders of Our Common Stock

As of February 24, 2023, there were approximately 143 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 Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to promote an understanding of the financial condition and results of operations and 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 and innovator in the orthopedic industry since our founding in 2004. In particular, we believe that we are a leader in the development, manufacturing, and sales of patient-specific products and instrumentation that are individually sized and shaped to fit each patient's unique knee and hip anatomy. The worldwide market for total knee and hip replacement products is approximately $17 billion annually. In the U.S. elective total joint procedures are shifting from the hospital to outpatient facilities and ambulatory surgery centers ("ASCs"). We believe that approximately 50% of all primary hip and knee procedures will be performed in ASCs within the next five years.

A key driver in the outpatient shift of orthopedic procedures is the ongoing changes by the Centers for Medicare & Medicaid Services ("CMS"). In recent years, CMS removed key musculoskeletal services from the inpatient-only list, including total knee arthroplasty in 2018 and total hip arthroplasty in 2020. CMS also continues to expand the ASCs covered procedure list, including total knee arthroplasty in 2020 and total hip arthroplasty in 2021. As healthcare costs rise, governments and government agencies, including CMS, are looking to reduce their healthcare expenditures markedly through reimbursement reductions and cost-shifting to patients.

On January 6, 2022, we announced the launch of our new Image-to-Implant® Platinum Services℠ Program, a premium service offering for the U.S. market. New to orthopedics, this program addresses the rapidly evolving demands of the healthcare marketplace where generic products are being commoditized and patients are increasingly willing to pay a premium for deluxe services. As of September 1, 2022, U.S. medical facility customers are only able to obtain our fully personalized iTotal Identity knee system through participation in our Image-to-Implant Platinum Services℠ Program.

Both Medicare and most commercial payors permit patients to pay out-of-pocket for non-covered, deluxe services. Through the Image-to-Implant® Platinum Services℠ Program, Conformis is bringing this approach to orthopedics by enabling participating medical facilities to establish and offer patients an out-of-pocket services upgrade to obtain the Company's fully personalized iTotal Identity™ knee system. Combined with our new Made-to-Measure Identity Imprint™ knee system, we believe that we now address multiple market segments within knee arthroplasty:

- the Identity Imprint™ knee system provides a data-informed high-quality knee implant system that provides a level of personalization through its patient-specific instruments ("PSI") and proprietary algorithms for pre-surgical planning, but is only available in pre-designed standard sizes, all at a price comparable to standard off-the-shelf options; and

- the Image-to-Implant® Platinum Services℠ Program gives patients in the United States the opportunity to upgrade to a fully-personalized iTotal Identity™ knee implant system by paying an incremental deluxe services fee.

As of December 31, 2022, we had sold a total of more than 149,000 knee implants, including more than 123,000 total knee implants and 26,000 partial knee implants. In multiple clinical studies, iTotal CR, our cruciate-

retaining total knee replacement implant, demonstrated superior clinical outcomes, including with respect to function, kinematics and objective functional measures, and greater patient satisfaction compared to those of standard, or off-the-shelf, implants that it was tested against. On August 16, 2021, the first procedure was performed using the Imprint knee replacement system. Imprint, available in both cruciate retaining ("CR") and posterior stabilized ("PS") implants, utilizes a proprietary algorithm to select the appropriate implant size from 12 standard sizes that most closely meet the geometric and anatomic requirements of the patient's knee based on the individual's CT scan. As with our personalized iTotal knee product line, Imprint uses our sterile Surgery-in-a-Box delivery system, which we believe provides ASCs and hospitals with greater procedural efficiency and improved sterilization cost savings over comparable systems. With the growing interest in our Imprint system from ASC customers, we have prioritized applying our porous-coated technology to the Imprint system which will be our first cementless TKA product offering. We are targeting a limited commercial launch of the porous-coated technology in the second half of 2023, however the launch may be delayed to the first half of 2024 due to regulatory or technical challenges.

On November 11, 2019, we entered full commercial launch of the Conformis personalized hip system, now branded as Cordera Rx. Since the launch of the personalized hip system, we have introduced multiple product line extensions including Cordera Standard, Cordera Pro and Cordera Match. In November 2022, we completed the first procedure using our Actera™ Hip System, a second hip stem within our hip portfolio. The system, designed for hip reconstruction, uses the cutting-edge tri-taper stem design, and features a range of sizes and angles derived from our data analytics. This cementless hip stem component features a proximally coated titanium spray with a hydroxyapatite layer to encourage initial and long-term fixation. We believe that the system's tri-taper stem design will enable surgeons to treat a broader range of patient anatomies and the shorter length options offer easier access to the femur while maintaining the fixation and integrity required for long term success of the implant. For the initial limited launch, the Actera™ Hip System will feature a range of standard sizes in both stem and cup components. We plan to launch future Actera™ line extensions that will offer additional personalization options for surgeons to choose what best fits their patients, even for complex anatomies. The new system is currently rolling out to select sites across the U.S., and we currently anticipate the full commercial launch to occur in mid-2023

All of our currently marketed knee and hip replacement products and related design software have been cleared by the U.S. Food and Drug Administration (the "FDA") under the premarket notification process of Section 510(k) of the federal Food, Drug, and Cosmetic Act (the "FDCA"). We 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, the United Arab Emirates, the Sultanate of Oman, Italy, Poland 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. We experienced significantly decreased demand for our products during the pandemic as healthcare providers and individuals de-prioritized and deferred medical procedures deemed to be elective, such as joint replacement procedures, which had a significant negative effect on our revenue.

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, Brazil, Suriname, Australia, the United Arab Emirates, the Sultanate of Oman, Italy, 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. In addition, our product revenue may fluctuate based on the product sales mix and mix of sales by geography. Our product revenue from international sales can be significantly impacted by fluctuations in foreign currency exchange rates, as our sales are denominated in the local currency in the countries in which we sell our products. We expect our product revenue to fluctuate from quarter-to-quarter due to a variety of factors, including seasonality, as we have historically experienced lower sales in the summer months and higher sales around year-end, the timing of the introduction of our new products, if any, and the impact of the buying patterns and implant volumes of medical facilities.

Royalty and licensing revenue for the year ended December 31, 2022, includes revenue generated from our Settlement and License agreement with Medacta USA, ("Medacta"), and $0.5 million generated from our license agreement (the "License Agreement") with Paragon 28. Royalty and licensing revenue for the year ended December 31, 2021, includes revenue of $15.0 million generated from our settlement with Stryker Corporation (“Stryker”), Wright Medical Technology, Inc. (“Wright Medical”), and Tornier, Inc. (“Tornier” and, collectively with Stryker and Wright Medical, the "Stryker Parties"), $25.0 million recognized under the Development and License Agreements with Stryker, and $1.0 million generated from our license agreement with Paragon 28. Ongoing royalty revenue is generated from our license agreement (the "MicroPort License Agreement") with MicroPort Orthopedics Inc., a wholly owned subsidiary of MicroPort Scientific Corporation, or collectively, MicroPort. The MicroPort 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.

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 PSI, or iJigs, tibial trays, and polyethylene tibia tray inserts used in our total knee implants, in our facility in Wilmington, Massachusetts. In regards to our hip products, our in-house manufacturing includes the stems, cups, and iJigs. 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, 2022, are legal fees payable to external counsel in connection with our patent licensing and enforcement activities related to the Settlement and License Agreement with Medacta.

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, manufacturing efficiencies, 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 reducing our manufacturing costs per unit, increasing our manufacturing efficiency, and increasing sales volume through the launch of Identity Imprint™ and our Image-to-Implant® Platinum Services℠ Program. 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;
- increased sales mix of our higher margin Identity ImprintTM product and an increased selling price as a result of our Image-to-Implant® Platinum Services℠ Program;
- 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 our CAD design activities that is performed in-house at our India facility; and
- developing new versions of our software used in the design of our joint replacement implants, which we believe will reduce costs associated with the design process;
- improving the efficiency of our internal manufacturing processes.

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 decrease in 2023 as part of our cost reduction plans. After 2023, we expect sales and marketing expense to increase primarily due to higher commissions. 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 decrease in 2023 as part of our cost reduction plans. After 2023, we expect research and development expense to remain relatively flat in absolute dollars.

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 to decrease in 2023 primarily due to lower litigation and other expenses associated with our cost reduction plans. After 2023, we expect general and administrative expense to increase as a result of higher personnel and freight expenses. Our general and administrative expense may fluctuate from period to period due to the timing and extent of the expenses.

Total other (expenses) income, 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, gain on forgiveness of PPP loan, loss on extinguishment of debt, income related to the development agreement with Stryker, 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.

Income tax provision

Income tax provision consists primarily of a tax provision for income taxes in India, a tax benefit from uncertain tax positions in Germany as a result of a lapse in the statue of limitations, and an immaterial amount of US state taxes. 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, 2022 and 2021

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

	2022		2021		2022 vs 2021	
Years Ended December 31,	Amount	As a% of Total Revenue	Amount	As a% of Total Revenue	$ Change	% Change
Revenue						
Product revenue	$ 57,825	93 %	$ 58,318	58 %	$ (493)	(1)%
Royalty and licensing	4,225	7	41,542	42	(37,317)	(90)
Total revenue	62,050	100	99,860	100	(37,810)	(38)
Cost of revenue	38,837	63	34,179	34	4,658	14
Gross profit	23,213	37	65,681	66	(42,468)	(65)
Operating expenses:						
Sales and marketing	25,308	41	24,904	25	404	2
Research and development	15,340	25	14,791	15	549	4
General and administrative	28,843	46	28,994	29	(151)	(1)
Total operating expenses	69,491	112	68,689	69	802	1
Loss from operations	(46,278)	(75)	(3,008)	(3)	(43,270)	(1,438)
Total other income/(expenses), net	(4,218)	(7)	686	1	(4,904)	(715)
Loss before income taxes	(50,496)	(81)	(2,322)	(2)	(48,174)	(2,075)
Income tax (benefit) provision	(23)	—	91	—	(114)	(125)
Net loss	$ (50,473)	(81)%	$ (2,413)	(2)%	$ (48,060)	(1,992)%

Product revenue. Product revenue was $57.8 million for the year ended December 31, 2022 compared to $58.3 million for the year ended December 31, 2021, a decrease of $0.5 million. The decrease in product revenue was primarily due to declines in orders from U.S. hospitals and the impact of foreign currency exchange rates offset by increases in orders from ambulatory surgery centers.

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):

	2022		2021		2022 vs 2021	
Years Ended December 31,	Amount	As a % of Product Revenue	Amount	As a % of Product Revenue	$ Change	% Change
United States	$ 50,527	87 %	$ 50,990	87 %	$ (463)	(1)%
Germany	3,215	6	5,422	9	(2,207)	(41)
Rest of world	4,083	7	1,906	4	2,177	114
Product revenue	$ 57,825	100 %	$ 58,318	100 %	$ (493)	(1)%

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 each of the years ended December 31, 2022 and 2021.

United States product revenue decreased $0.5 million to $50.5 million or 1% year over year. The decrease in product revenue was primarily due to declines in orders from U.S. hospitals offset by increases in orders from ambulatory surgery centers. Following the September 1, 2022 transition to the new business model, we have seen

a reduction in our orders as existing customers migrate to the new product and service offering. Additionally, some of our existing customers have chosen not to offer our fully personalized iTotal Identity product given it will require an out-of-pocket patient pay upgrade and some have chosen not to order Identity Imprint given it is not a fully personalized knee system. Germany product revenue decreased $2.2 million to $3.2 million, or 41% year over year on a reported basis and 34% on a constant currency basis. We believe the decline was primarily due to the shift in certain distributors that were previously managed by Germany, reimbursement denials from Medizinischer Dienst der Krankenversicherung ("MDK"), and foreign currency exchange rates. Rest of World product revenue increased $2.2 million to $4.1 million, or 114% year-over-year on a reported basis and 132% on a constant currency basis. The increase is primarily due to the shift in distributors that were previously managed by Germany now being managed by other countries, an increase in elective surgeries in the UK which were lower in the prior period as a result of the COVID-19 pandemic, and growth in Australia.

Royalty and licensing revenue. Royalty and licensing revenue was $4.2 million for the year ended December 31, 2022 compared to $41.5 million for the year ended December 31, 2021, a decrease of $37.3 million or 90%. The decrease in royalty and licensing revenue was driven by revenue recognized in the prior year which included $25.0 million in revenue recognized in connection with 510(k) clearance from the FDA for the achievement of the third of three milestones under the License Agreement with Stryker, $15.0 million in revenue recognized under the Settlement and License Agreement with the Stryker Parties, and $1.0 million in revenue recognized under the License Agreement with Paragon 28. Royalty and licensing revenue for the year ended December 31, 2022 includes $0.5 million in revenue recognized under the License Agreement with Paragon 28, and revenue recognized under the settlement agreement with Medacta.

Cost of revenue, gross profit and gross margin. Cost of revenue was $38.8 million for the year ended December 31, 2022 compared to $34.2 million for the year ended December 31, 2021, an increase of $4.7 million or 14%. The increase was due primarily to higher legal fees as 2022 included outside counsel expense in connection with our patent licensing and enforcement activities related to the Settlement and License Agreement with Medacta, higher scrap and cancelled case inventory expenses, and increased labor and material costs. Gross profit was $23.2 million for the year ended December 31, 2022 compared to $65.7 million for the year ended December 31, 2021, a decrease of $42.5 million or 65%. Gross margin was 37% for the year ended December 31, 2022 compared to 66% for the year ended December 31, 2021, a decrease of 2,840 basis points. The decrease in gross margin was driven primarily by licensing revenue recognized in the prior year under the Development and License Agreements with Stryker and the Settlement and License Agreement with the Stryker Parties.

Sales and marketing. Sales and marketing expense was $25.3 million for the year ended December 31, 2022 compared to $24.9 million for the year ended December 31, 2021, an increase of $0.4 million or 2%. The increase was due primarily to increases in marketing expense of $0.6 million, commission expense of $0.3 million and depreciation expense of $0.2 million, which was partially offset by decreases in professional services of $0.2 million, legal expense of 0.2 million, travel and entertainment expense of $0.1 million, personnel related costs of $0.1 million and instrumentation and supplies of $0.1 million. Sales and marketing expense increased as a percentage of total revenue to 41% for the year ended December 31, 2022 compared to 25% for the year ended December 31, 2021.

Research and development. Research and development expense was $15.3 million for the year ended December 31, 2022 compared to $14.8 million for the year ended December 31, 2021, an increase of $0.5 million or 4%. The increase was due primarily to an increase in professional and outside services of $1.0 million, and a reduction of $0.7 million of cost allocated to the advance on research and development, partially offset by lower personnel related costs of $0.8 million, project prototype and supply costs of $0.1 million, clinical trial expense of $0.1 million, and lower other costs of $0.2 million. Research and development expense increased as a percentage of total revenue to 25% for the year ended December 31, 2022 from 15% for the year ended December 31, 2021.

General and administrative. General and administrative expense was $28.8 million for the year ended December 31, 2022 compared to $29.0 million for the year ended December 31, 2021, a decrease of $0.2 million or 1%. The decrease was primarily due to a decrease in legal fees of $1.8 million and a decrease in insurance costs of $0.5 million, partially offset by increases in freight costs of $1.0 million, professional services of $0.4 million, bad debt expense of $0.4 million, and technology expenses of $0.3 million. General and administrative expense increased as a percentage of total revenue to 46% for the years ended December 31, 2022 from 29% for the year ended December 31, 2021.

Total other (expenses) income, net. Total other (expenses) income, net was $4.2 million of other expenses for the year ended December 31, 2022 compared to other income of $0.7 million for the year ended December 31, 2021, a change of $4.9 million, or 715%. The change was primarily due to the prior year recognition of a gain on forgiveness of PPP loan of $4.8 million, and $2.5 million for the unused portion of the advance on

research and development under the Development Agreement with Stryker, offset by lower interest expense of $1.5 million resulting from a loss on the extinguishment of debt in 2021, and a decrease of $0.4 million in foreign currency exchange transaction loss.

Income taxes. Income tax benefit was $(23,000) for the year ended December 31, 2022 and income tax provision was $91,000 for the year ended December 31, 2021. We continue to generate losses for U.S. federal and state tax purposes and have net operating loss carryforwards creating a deferred tax asset. We maintain a full valuation allowance for deferred tax assets.

Comparison of the years ended December 31, 2021 and 2020

For a discussion of the comparison of our results of operations for the fiscal years ended December 31, 2021 and 2020, refer to the Management's Discussion and Analysis of Financial Condition and Results of Operations section in our previously filed Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Liquidity, capital resources and plan of operations

Reverse Stock Split

On October 26, 2022, our Board of Directors approved a 1-for-25 reverse stock split of our Common Stock ("Reverse Stock Split"), which was implemented in November 2022. As a result of the Reverse Stock Split, each of the holders of our Common Stock received one (1) new share of Common Stock for every twenty-five (25) shares such shareholder held immediately prior. No fractional shares were issued as a result of the Reverse Stock Split. Any fractional shares that would have otherwise resulted from the Reverse Stock Split were rounded up to the next whole number of shares. The Reverse Stock Split also affected the Company's outstanding stock options and warrants and resulted in the shares underlying such instruments being reduced and the exercise price being increased proportionately to the Reverse Stock Split ratio.

All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated. The total number of our authorized shares of preferred stock was not affected by the foregoing. However, the total number of our authorized common stock was decreased to 20,000,000 after giving effect to the Reverse Stock Split. In connection with the Reverse Stock Split, there was no change in the par value per share of $0.00001.

Sources of liquidity and funding requirements

From our inception in June 2004 through the year ended December 31, 2022, 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, 2022, we had an accumulated deficit of $581.3 million.

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

- expansion of our sales and marketing efforts, including the expanded advertising of our Platinum Services℠ Program;
- expansion of our manufacturing capacity;
- funding research and development activities related to new and existing products, including our porous-coated technology for the Imprint system and Actera™ line extensions;
- pursuing and maintaining appropriate regulatory clearances and approvals for our existing products and any new products that we may develop; and
- enforcing our intellectual property rights and pursuing our claims against Aetna.

We anticipate that our principal sources of funds in the future will be revenue generated from the sales of our products, potential future capital raises through the issuance of equity or other securities, available sales of shares under the Sales Agreement, or potential debt financings, 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.

On March 23, 2020, we filed a shelf registration statement on Form S-3 (the "Shelf Registration Statement"), which was declared effective by the SEC on August 5, 2020. Under the Shelf Registration Statement, we are 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 our own account in one or more offerings. The 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 our common stock and entered into an ATM issuance sales agreement (the "Sales Agreement"), with Cowen and Company, LLC ("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. Under the Sales Agreement, 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 have provided Cowen with customary indemnification rights. Any shares of Common Stock offered pursuant to the Sales Agreement will be offered and sold pursuant to the 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 the date thereof, we have not sold any shares under the Sales Agreement.

On December 17, 2018, we entered into a stock purchase agreement (the "Stock Purchase Agreement") with Lincoln Park Capital ("LPC"). Upon entering into the Stock Purchase Agreement, we sold 76,879 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 14,177 shares to LPC (adjusted for the 1-for-25 reverse stock split). We had 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 controlled the timing of any sales to LPC and LPC was 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 were no upper limits to the price per share LPC would 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 was to 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 was not 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 were associated with the Stock Purchase Agreement and LPC 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 expired on January 1, 2022.

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) 340,483 shares of its common stock and accompanying warrants to purchase up to 340,483 shares of common stock and (ii) pre-funded warrants to

purchase up to 379,718 shares of common stock and accompanying warrants to purchase up to 379,718 shares of common stock in a registered direct offering (adjusted for the 1-for-25 reverse stock split) 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 $23.95 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 $0.0025 per share and were exercisable until all of the pre-funded warrants were exercised in full. As of March 31, 2021, all pre-funded warrants were exercised. The warrants became exercisable immediately upon issuance, have an exercise price of $21.87 per share (adjusted for the 1-for-25 reverse stock split), and will expire five years from the date of issuance. As of December 31, 2022, approximately 240,000 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 November 22, 2021, we entered into a Credit and Security Agreement (the “New Credit Agreement”) with MidCap Financial Services, LLC (“MidCap Financial Services”), as servicer for MidCap Financial Trust to refinance the Company's existing senior secured indebtedness. The New Credit Agreement provides for a five-year, $21 million secured term loan facility (the “Term Facility”), and replaces our existing credit facility under the 2019 Secured Loan Agreement, with Innovatus, as collateral agent and lender, East West Bank and other lenders party thereto (collectively, the "Lenders"). We used the proceeds from the debt financings to pay off our existing credit facility under the 2019 Secured Loan Agreement with the Lenders.

The New Credit Agreement contains customary affirmative and negative covenants, including limitations on our ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, pay subordinated indebtedness and enter into affiliate transactions. In addition, the New Credit Agreement contains a minimum liquidity covenant requiring the us to maintain unrestricted cash and cash equivalents in excess of $4.0 million. The New Credit Agreement also includes events of default customary for facilities of this type and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Term Facility may be accelerated. As of December 31, 2022, we were not in breach of covenants under the New Credit Agreement. For further information regarding the New Credit 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.

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 June 30, 2021, we had successfully completed the third of three milestones with Stryker and received $11.0 million, for a total aggregate received of $16.0 million for achievement of these milestones. Under the long-term Distribution Agreement, we supply patient-specific instrumentation to Stryker.

The Coronavirus Aid, Relief, and Economic Security Act (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 (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 was a fixed rate of 1% per annum. We were required to make one payment of all outstanding principal plus all accrued unpaid interest on April 9, 2022 (the "Maturity Date"). We were required to 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. According to the terms of the PPP, all or a portion of the loan as well as any accrued interest was eligible to be fully forgiven if the funds were used for payroll costs, 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. On March 4, 2021, our lender submitted our application to the SBA for their review and on June 30, 2021, we received notification through our lender that the SBA had rendered a final decision regarding its review of the PPP loan forgiveness application, fully approving the loan forgiveness application as of June 28, 2021.

On November 8, 2022 we entered into a Settlement and License Agreement with Medacta, pursuant to which the parties agreed to terms for resolving the then-existing patent disputes. In consideration of the licenses, releases, covenants and other immunities granted by us to Medacta, Medacta was required to pay us a fee promptly after execution of the Settlement and License Agreement, which was received in full on December 12, 2022. The agreement provides for the grant of the licenses, covenants-not-to-sue, releases, and other significant deliverables upon receipt of the payment from Medacta.

On February 17, 2021, we closed an offering of our common stock under the Shelf Registration Statement and issued and sold 3,238,095 shares of our common stock at a public offering price of $26.25 per share (adjusted for the 1-for-25 reverse stock split), for aggregate net proceeds of approximately $79.6 million. We intend 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 our secured term loan facility, working capital and capital expenditures.

On April 8, 2021, we entered into a License Agreement with Paragon 28, granting Paragon 28 a non-exclusive license under a subset of our U.S. patents for the use of patient-specific instruments with off-the-shelf implants. In connection with this License Agreement, we recognized revenue of $1.0 million during the quarter ended June 30, 2021 and $0.5 million during the quarter ended March 31, 2022.

On June 30, 2021 we entered into a Settlement and License Agreement with the Stryker Parties, pursuant to which the parties have agreed to terms for resolving all of their existing patent disputes. Under the Settlement and License Agreement, we granted to the Stryker Parties a royalty-free, non-exclusive, worldwide license to certain of our patents for the Stryker Parties' patient-specific instrumentation used with off-the-shelf knee, hip, and shoulder implants. Under the agreement, the Stryker Parties are required to pay us a one-time payment of $15.0 million no later than October 15, 2021. The payment was received in October 2021.

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

At December 31, 2022, we had cash and cash equivalents of $48.7 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 over the next twelve months with existing cash and cash equivalents as of December 31, 2022, anticipated revenue from operations, revenue that may be generated in connection with licensing intellectual property, available sales of shares under the Sales Agreement, funds from additional equity or debt financing. 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 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 through April 2020, we have eliminated, reduced, or are deferring significant non-essential expense including sales, marketing, quality, clinical, regulatory and all general and administrative 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,			
	2022	2021	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$ (50,153)	$ (8,399)	$ (41,754)	(497)%
Investing activities	(1,918)	(2,300)	382	17
Financing activities	—	82,803	(82,803)	(100)
Effect of exchange rate on cash	82	(121)	203	168
Total	$ (51,989)	$ 71,983	$ (123,972)	(172)%

Net cash used in operating activities. Net cash used in operating activities was $50.2 million for the year ended December 31, 2022 and $8.4 million for the year ended December 31, 2021, an increase in use of $41.8 million. The $41.8 million increase in net cash used in operating activities was primarily affected by an increase in net loss of $48.1 million, an increase in accounts receivable of $0.5 million, an increase in prepaid expense and other assets of $0.6 million, an increase in inventory of $1.1 million, an increase in royalty and licensing receivable of $0.8 million, an increase in advance on research and development under the Stryker Agreements of $3.2 million, an increase in contract liability of $14.0 million, a decrease in accounts payable, accrued expenses and other liabilities of $8.4 million. Non-cash reconciling items include an increase on the loss on extinguishment of debt of $1.1 million, an increase on gain on forgiveness of PPP loan of $4.8 million, a decrease in unrealized foreign exchange gain/loss of $1.1 million, and a decrease in stock compensation expense of $1.7 million.

Net cash used in investing activities. Net cash used in investing activities was $1.9 million for the year ended December 31, 2022 compared to $2.3 million cash used in investing activities for the year ended December 31, 2021, a decrease of $0.4 million. The decrease is due to a decrease in costs related to the acquisition of property, plant, and equipment.

Net cash provided by financing activities. Net cash provided by financing activities was $— million for the year ended December 31, 2022 and $82.8 million for the year ended December 31, 2021, a decrease of $82.8 million. Net cash provided by financing activities in the prior year included $79.6 million of net proceeds from the issuance of common stock under the Shelf Registration Statement and $5.3 million of proceeds from the exercise of common stock warrants.

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 0.8% to 6.2%. We incurred aggregate revenue share expense, included in research and development, including all amounts payable under our scientific advisory board revenue share agreements of $2.2 million during the year ended December 31, 2022, and representing 3.8% of product revenue, $2.2 million during the year ended December 31, 2021, representing 3.7% 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, 2022, 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, Brazil, Australia, the United Arab Emirates, the Sultanate of Oman, Italy, 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.

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”).

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.

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.

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.

Under ASC 606, the individual rights to license certain of our patents are accounted for as a single performance obligation. The earnings process is complete and revenue is recognized at a point in time, that is, 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.

Under the long-term Distribution Agreement with Stryker, we supply patient specific instrumentation and revenue is recognized at a point in time, that is, when Stryker obtains control of the products.

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. We concluded that Stryker meets the definition of a customer for a portion of the obligations under the Stryker Agreements. There was no contract liability balance as of January 1, 2022. As of January 1, 2021, the contract liability balance was $14.0 million, which was related to consideration received from the customer under the Asset Purchase Agreement and Development Agreement. We concluded the license rights under the License Agreement were functional and would be recognized at the point in time when 510(k) clearance was received from the FDA as required under Milestone 3 in the License Agreement, or upon termination by Stryker and Stryker's election to purchase the license rights. On April 19, 2021, we achieved the third of three milestones under the License Agreement when it received 510(k) clearance from the FDA and received $11.0 million from Stryker. In connection with the 510(k) clearance, we recognized as royalty and license revenue the $14.0 million that was previously deferred as contract liability, plus the $11.0 million payment received, for a total aggregate of $25.0 million during the quarter ended June 30, 2021.

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, 2022, and 2021, we recognized provisions of $4.7 million and $2.6 million, respectively, to adjust our inventory value to the lower of cost or net realizable value for excess and obsolete reserves, and 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. If changes in circumstances lead us to believe that any of our long-lived assets may be impaired, we will test the asset group for recoverability, by evaluating whether the estimated undiscounted cash flows, including estimated residual value, generated from the asset group are sufficient to support the carrying value of the assets. During the quarters ended March 31, 2022, June 30, 2022 and September 30, 2022 and December 31, 2022, we had experienced a significant decrease in our stock price and incurred current-period operating losses associated with our asset group, 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 cash flow estimates or the significant operating assumptions upon which they are based change in the future, we may be required to record impairment charges. During the years ended December 31, 2022 and 2021, no such impairment charges were recognized.

Income taxes

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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Conformis, Inc.

Opinion on the financial statements
We have audited the accompanying consolidated balance sheets of Conformis, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive (loss) income, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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.

Management's assertion of the Company's ability to continue as a going concern

As described further in note A to the financial statements, the Company has an accumulated deficit and recurring losses. Management has assessed, based on its operating plan, that the Company's current cash and cash equivalents and anticipated revenue from operations are sufficient to satisfy the Company's obligations as they come due for at least one year from the issuance date of these financial statements.

We determined management's assessment over the Company's ability to continue as a going concern is a critical audit matter.

The principal consideration for our determination that the Company's ability to continue as a going concern is a critical audit matter is the estimation uncertainty related to the Company's forecasted cash flows, which requires significant auditor judgment in evaluating the reasonableness of such forecasts.

Our audit procedures related to management's assessment over its ability to continue as a going concern included the following, among others:

- We tested the reasonableness of the Company's cash flow projections in management's assessment for consistency with historical data and changes in the business.
- We performed sensitivity analyses on the projected revenue growth rates and operating margins used in the Company's cash flow projections to evaluate the impact on the conclusions reached by management.

/s/ GRANT THORNTON LLP

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

Boston, Massachusetts
March 1, 2023

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

	December 31, 2022	December 31, 2021
Assets		
Current Assets		
Cash and cash equivalents	$ 48,667	$ 100,556
Accounts receivable, net	9,773	9,079
Royalty and licensing receivable	134	280
Inventories	18,910	15,204
Prepaid expenses and other current assets	1,785	1,764
Total current assets	79,269	126,883
Property and equipment, net	8,154	10,268
Operating right-of-use assets	6,078	7,536
Other Assets		
Restricted cash	462	562
Other long-term assets	85	92
Total assets	$ 94,048	$ 145,341
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 4,163	$ 6,557
Accrued expenses	7,978	9,576
Operating lease liabilities	1,932	1,830
Total current liabilities	14,073	17,963
Other long-term liabilities	230	—
Long-term debt, less debt issuance costs	20,563	20,355
Operating lease liabilities	5,003	6,471
Total liabilities	39,869	44,789
Commitments and contingencies (Note H)		
Stockholders’ equity		
Preferred stock, $0.00001 par value:		
Authorized: 5,000,000 shares authorized at December 31, 2022 and December 31, 2021; no shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, $0.00001 par value:		
Authorized: 20,000,000 shares authorized at December 31, 2022 and December 31, 2021; 7,502,462 and 7,441,668 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively*	—	2
Additional paid-in capital*	634,647	632,513
Accumulated deficit	(581,324)	(530,851)
Accumulated other comprehensive income (loss)	856	(1,112)
Total stockholders’ equity	54,179	100,552
Total liabilities and stockholders’ equity	$ 94,048	$ 145,341

*Adjusted for the 1-for-25 reverse stock split

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,	
	2022	2021
Revenue		
Product	$ 57,825	$ 58,318
Royalty and licensing	4,225	41,542
Total revenue	62,050	99,860
Cost of revenue	38,837	34,179
Gross profit	23,213	65,681
Operating expenses		
Sales and marketing	25,308	24,904
Research and development	15,340	14,791
General and administrative	28,843	28,994
Total operating expenses	69,491	68,689
Loss from operations	(46,278)	(3,008)
Other income and expenses		
Interest income	53	97
Interest expense	(2,019)	(3,496)
Foreign currency exchange transaction loss	(2,252)	(3,167)
Other income	—	7,252
Total other (loss) income	(4,218)	686
Loss before income taxes	(50,496)	(2,322)
Income tax (benefit) provision	(23)	91
Net loss	$ (50,473)	$ (2,413)
Net loss per share - basic and diluted*	$ (6.99)	$ (0.36)
Weighted average common shares outstanding - basic and diluted*	7,219,368	6,668,530

*Adjusted for the 1-for-25 reverse stock split

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

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive (Loss) Income
(in thousands)

	Years Ended December 31,	
	2022	2021
Net loss	$ (50,473)	$ (2,413)
Other comprehensive income		
Foreign currency translation adjustments	1,968	2,888
Comprehensive (loss) income	$ (48,505)	$ 475

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, 2020	3,821,830	$ 1	$ 543,809	$ (528,438)	$ (4,000)	$ 11,372
Issuance of common stock—restricted stock	141,541	—	—	—	—	$ —
Issuance of common stock at public offering, less issuance costs of $5.4 million	3,238,095	1	79,636	—	—	79,637
Issuance of common stock upon exercise of common stock warrants	240,202	—	5,253	—	—	5,253
Compensation expense related to issued stock options and restricted stock awards	—	—	3,815	—	—	3,815
Net loss	—	—	—	(2,413)	—	(2,413)
Other comprehensive income	—	—	—	—	2,888	2,888
Balance, December 31, 2021	7,441,668	$ 2	$ 632,513	$ (530,851)	$ (1,112)	$ 100,552
Issuance of common stock—restricted stock	60,794	—	—	—	—	—
Effect of the 1-for 25 reverse stock split	—	(2)	2	—	—	—
Compensation expense related to issued stock options and restricted stock awards	—	—	2,132	—	—	2,132
Net loss	—	—	—	(50,473)	—	(50,473)
Other comprehensive income	—	—	—	—	1,968	1,968
Balance, December 31, 2022	7,502,462	$ —	$ 634,647	$ (581,324)	$ 856	$ 54,179

*Adjusted for the 1-for-25 reverse stock split

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,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (50,473)	$ (2,413)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	4,032	4,273
Stock-based compensation expense	2,132	3,815
Unrealized foreign exchange loss	1,888	3,009
Non-cash lease expense	1,520	1,443
Provision for bad debts on trade receivables	396	48
Gain on forgiveness of PPP loan	—	(4,772)
Loss on extinguishment of debt	—	1,068
Non-cash interest expense	167	738
Changes in operating assets and liabilities:		
Accounts receivable	(1,090)	(612)
Royalty and licensing receivable	145	976
Inventories	(3,704)	(2,619)
Prepaid expenses and other assets	(15)	546
Accounts payable, accrued expenses, and other liabilities	(5,151)	3,269
Contract liability	—	(14,000)
Advance on research and development	—	(3,168)
Net cash used in operating activities	(50,153)	(8,399)
Cash flows from investing activities:		
Acquisition of property and equipment	(1,918)	(2,300)
Net cash used in investing activities	(1,918)	(2,300)
Cash flows from financing activities:		
Proceeds from exercise of common stock warrants	—	5,253
Debt issuance costs	—	(659)
Loss on extinguishment of debt	—	(1,216)
Proceeds from issuance of debt	—	21,000
Payments on long-term debt	—	(21,212)
Net proceeds from issuance of common stock	—	79,637
Net cash provided by financing activities	—	82,803
Foreign exchange effect on cash and cash equivalents	82	(121)
(Decrease) increase in cash, cash equivalents, and restricted cash	(51,989)	71,983
Cash, cash equivalents, and restricted cash beginning of period	101,118	29,135
Cash, cash equivalents, and restricted cash end of period	$ 49,129	$ 101,118
Supplemental information:		
Cash paid for interest	1,656	1,463
Non-cash investing and financing activities		
Operating leases right-of-use assets obtained in exchange for lease obligations	63	3,763

The accompanying notes are an integral part of these 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 also offers Identity Imprint, a new line of total knee replacement products that utilizes a proprietary algorithm to select the implant size that most closely meets the geometric and anatomic requirements of the patient's knee. Conformis' sterile, just-in-time, Surgery-in-a-Box delivery system is available with all of its implants and personalized, single-use instruments. 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, its Conformis hip system in 2018, and its Identity Imprint in 2021. The Company has its corporate offices in Billerica, Massachusetts.

Liquidity and operations

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.

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 recurring losses for the years ended December 31, 2022 and 2021. At December 31, 2022, the Company had an accumulated deficit of $581.3 million and cash and cash equivalents of $48.7 million, and $0.5 million in restricted cash allocated to a lease deposit.

The Company currently expects that its existing cash and cash equivalents as of the date hereof and anticipated revenue from operations will enable the Company to fund its operations, capital expenditure requirements and debt service for the 12 months following the date of this filing. However, for the Company to meet its operating plan, the Company expects that revenue growth, margin improvements and leveraging operating expenses will be necessary. To enhance its liquidity position, the Company has taken measures to manage its expenses, will continue to monetize the Company's intellectual property, and will evaluate additional equity or debt financing opportunities. Whether the Company ultimately consummates such an additional equity and/or debt financing will depend on many factors, including market conditions. It cannot be assured that the Company will be successful in raising such additional financing, or in achieving the revenue growth, margin improvements and operating expense leverage.

On October 26, 2022, the Company's Board of Directors approved a 1-for-25 reverse stock split of the Company's common stock (the "Reverse Stock Split") which was implemented in November 2022. All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated. There were no fractional shares issued as a result of the Reverse Split. All fractional shares as a result of the Reverse Split were rounded up to the nearest whole number. The total number of the Company's authorized shares of preferred stock was not affected by the foregoing. However, the total number of the Company's authorized common stock was decreased to 20,000,000 after giving effect to the Reverse Stock Split. For further information regarding this Reverse Stock Split, see "**Note J—**Stockholders' Equity".

On November 22, 2021, the Company and its subsidiary, ImaTx, Inc., entered into a Credit and Security Agreement (the “New Credit Agreement”) with MidCap Financial Trust (“MidCap”), as agent, and certain lender parties thereto. The New Credit Agreement provides for a five-year, $21 million secured term loan facility (the “Term Facility”). The New Credit Agreement refinanced and replaced the Company’s prior 2019 secured credit facility with Innovatus (the “2019 Secured Loan Agreement”). The Company used the amounts drawn under the New Credit Agreement to repay all outstanding obligations under the 2019 Secured Loan Agreement, which 2019 Secured Credit Loan Agreement has been terminated. For further information regarding the 2019 Secured Loan Agreement and the New Credit Agreement see “Note I—Debt and Notes Payable”.

On February 17, 2021, the Company closed an offering of its common stock under the Company's shelf registration statement on Form S-3, pursuant to which the Company issued and sold 3,238,095 shares of its common stock at a public offering price of $26.25 per share (adjusted for the 1-for-25 reverse stock split), for aggregate net proceeds of approximately $79.6 million. For further information regarding this public offering, see "**Note J—**Stockholders' Equity".

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 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. More recently, in the third and fourth quarters of 2021, the Company experienced higher levels of deferred and rescheduled knee and hip procedures as a result of the surge in COVID-19 cases associated with the Delta and Omicron variants. During the first quarter of 2022, United States case counts peaked in January and then trended downward for the remainder of the year. 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 continue to 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 which mitigates potential risks related to concentration. The Company had $1.2 million as of December 31, 2022 and $0.6 million as of December 31, 2021 held in foreign bank accounts, that are not federally insured.

The Company and its contract manufacturers rely on sole source suppliers and service providers for certain components. A shortage or stoppage of shipments of the materials or components that the Company purchases could result in a delay in production or adversely affect the Company’s operating results.

For the year ended December 31, 2022, no customer represented greater than 10% of total revenue. For the year ended December 31, 2021, Stryker Corporation (“Stryker”), Wright Medical Technology, Inc. (“Wright Medical”), and Tornier, Inc. (“Tornier,” and collectively with Stryker and Wright Medical, the "Stryker Parties") represented 40% of total revenue. As of December 31, 2022 and 2021, 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. 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, 2022, and $0.6 million as of December 31, 2021. 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, 2022	December 31, 2021
Cash and cash equivalents	$ 48,667	$ 100,556
Restricted cash	462	562
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 49,129	$ 101,118

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 current 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") Topic 606, Revenue from Contracts with Customers ("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, 2022 and 2021, the Company recognized provisions of $4.7 million and $2.6 million, respectively, to adjust its inventory value

to the lower of cost or net realizable value for excess and obsolete reserves, and 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. If changes in circumstances lead the Company to believe that any of its long-lived assets may be impaired, the Company will test the asset group for recoverability, by evaluating whether the estimated undiscounted cash flows, including estimated residual value, generated from the asset group are sufficient to support the carrying value of the assets. During the quarters ended March 31, 2022, June 30, 2022, September 30, 2022 and December 31, 2022, the Company had experienced a significant decrease in its stock price and incurred current-period operating losses associated with its asset group, 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 cash flow estimates or the significant operating assumptions upon which they are based change in the future, the Company may be required to record impairment charges. During the years ended December 31, 2022 and 2021, no such impairment charges were recognized.

Leases

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 anticipated term, inclusive of renewals of 12 months or less are not recorded on the balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

The Company has elected the hindsight practical expedient to determine the lease term for existing leases. This practical expedient enables an entity to use hindsight in determining the lease term when considering options to extend and terminate leases as well as purchase the underlying assets. The operating lease right-of-use assets are subsequently assessed for impairment in accordance with the Company's accounting policy for long-lived assets.

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, 2022. 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.

Under the long-term Distribution Agreement with Stryker, the Company supplies patient specific instrumentation to Stryker and revenue is recognized at a point in time, that is, when Stryker obtains control of the products.

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, 2022, the Company had $0.2 million of contract liabilities recorded on the Consolidated Balance Sheets derived from contract with customers. There were no contract assets recorded at December 31, 2022. The Company did not have any contract assets or liabilities recorded at December 31, 2021.

Royalty and Licensing Revenue Recognition

The Company receives ongoing sales-based royalties under its license agreement (the "MicroPort License Agreement") with MicroPort Orthopedics Inc., a wholly owned subsidiary of MicroPort Scientific Corporation, (collectively, "MicroPort"). Royalty revenue is recorded at the expected value of the royalty revenue.

On September 30, 2019 the Company entered into an Asset Purchase Agreement with Howmedica Osteonics Corp., a wholly-owned subsidiary of Stryker. In connection with entering into the Asset Purchase Agreement, the Company also entered into a Development Agreement, a License Agreement, and other ancillary agreements contemplated by the Asset Purchase Agreement with Stryker (the "Stryker Agreements"). The Company determined that the Asset Purchase Agreement and the License Agreement, are within the scope of ASC 606. Under the Asset Purchase Agreement and License Agreement, 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 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 of 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. The Company has concluded that Stryker meets the definition of a customer for a portion of the obligations under the Stryker Agreements. There was no contract liability balance as of January 1, 2022. As of January 1, 2021, the contract liability balance was $14.0 million, which was related to consideration received from the customer under the Asset Purchase Agreement and Development Agreement. The Company concluded the license rights under the License Agreement were

functional and would be recognized at the point in time when 510(k) clearance was received from the FDA as required under Milestone 3 in the License Agreement, or upon termination by Stryker and Stryker's election to purchase the license rights. On April 19, 2021, the Company achieved the third of three milestones under the License Agreement when it received 510(k) clearance from the FDA and received $11.0 million from Stryker. In connection with the 510(k) clearance, the Company recognized as royalty and license revenue the $14.0 million that was previously deferred as contract liability, plus the $11.0 million payment received, for a total aggregate of $25.0 million during the quarter ended June 30, 2021. There are no amounts recorded as contract liability related to the Stryker agreements as of December 31, 2022. In addition, during the quarter ended June 30, 2021, the Company recorded $2.5 million in other income for the remaining portion of the advance on research and development, that was not used to offset against research and development expenses.

On April 8, 2021, the Company entered into a license agreement (the “License Agreement”) with Paragon 28, Inc. ("Paragon 28"), granting Paragon 28 a non-exclusive license under a subset of the Company's U.S. patents for the use of patient-specific instruments with off-the-shelf implants in Paragon 28’s APEX 3D Total Ankle Replacement System. In consideration for the license, the Company received $0.5 million upon execution of the License Agreement, another $0.5 million in October 2021, and received an additional $0.5 million from Paragon 28 on April 7, 2022. In connection with this License Agreement, the Company recognized revenue of $1.0 million during the quarter ended June 30, 2021. The remaining $0.5 million was recognized as revenue during the quarter ended March 31, 2022.

On June 30, 2021 the Company entered into a settlement and license agreement (the “Settlement and License Agreement”) with the Stryker Parties, pursuant to which the parties agreed to terms for resolving all of their then-existing patent disputes. In consideration of the licenses, releases, covenants and other immunities granted by the Company to the Stryker Parties, the Stryker Parties were required to make a one-time payment to the Company of $15.0 million no later than October 15, 2021. The agreement provides for the grant of the licenses, covenants-not-to-sue, releases, and other 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 the Stryker Parties is not separately identifiable from other promises in the agreement. As a result, the Company accounts for the promises in the Settlement and License Agreement as a single performance obligation. The Stryker Parties 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 $15.0 million during the quarter ended June 30, 2021 and payment in the same amount was received from the Stryker Parties on October 15, 2021. See “Note H—Commitments and Contingencies, Legal proceedings” for further discussion of the Stryker Parties settlement.

On November 8, 2022 the Company entered into a Settlement and License Agreement with Medacta USA, ("Medacta"), 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 Medacta, Medacta was required to pay the Company a fee promptly after execution of the Settlement and License Agreement, which was received in full on December 12, 2022. The agreement provides for the grant of the licenses, covenants-not-to-sue, releases, and other significant deliverables upon receipt of the payment from Medacta. 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 Medacta 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. Medacta legally obtained control of the license and other rights upon payment to Conformis. As such, the earnings process is complete and revenue was recognized upon receipt of the payment, 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 licensing revenue during the year ended December 31, 2022. See “Note H—Commitments and Contingencies, Legal proceedings” for further discussion of the Medacta 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, 2022 and 2021 (in thousands):

	Years Ended December 31,	
	2022	2021
Beginning Balance	$ 79	$ 81
Provision related to current period sales	126	107
Payments or credits issued to customer	(97)	(109)
Ending Balance	$ 108	$ 79

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 $4.1 million and $3.1 million for the years ended December 31, 2022 and 2021, 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 ("PSI") to be used with Stryker's off-the-shelf knee implant, design freeze of the PSI, and FDA 510(k) clearance of the developed product. As of December 31, 2021, the Company completed all three milestones under the Development Agreement.

The Company recognized $0.7 million in Research and development expense for the year ended December 31, 2021, 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 all three milestones. During the quarter ended June 30, 2021, the Company recorded $2.5 million in other income for the remaining portion of the advance on research and development, that was not used to offset against research and development expenses.

Research and development expense

The Company's research and development costs 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 cost 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. 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 $0.6 million and $0.2 million for the years ended December 31, 2022 and 2021, respectively.

Segment reporting

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

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 analyzed these aspects of the CARES Act and it had no material impact on its consolidated financial statements.

On December 27, 2020, the U.S government enacted the Consolidated Appropriations Act, 2021 (the "Appropriations 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 Appropriations Act in regards to expenses related to the PPP loan proceeds, which previously would have been non-deductible.

The Inflation Reduction Act (IRA) was enacted on August 16, 2022. Based on review of the IRA, the Company does not expect any impact to its tax provision. In particular, the Company does not expect to pay Corporate Alternative Minimum Tax (CAMT) in future years based on its projected losses and not reaching the income thresholds. The IRA introduces a 15% CAMT for corporations whose average annual adjusted financial statement income for any consecutive three-tax-year period preceding the tax year exceeds $1 billion starting in 2023.

Stock-based compensation

The Company accounts for stock-based compensation in accordance with ASC 718, Stock Based Compensation ("ASC 718"). 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, 2022	2021
Numerator:		
Numerator for basic and diluted loss per share:		
Net loss	$ (50,473)	$ (2,413)
Denominator:		
Denominator for basic loss per share:		
Weighted average shares*	7,219,368	6,668,530
Basic loss per share attributable to Conformis, Inc. stockholders*	$ (6.99)	$ (0.36)
Diluted loss per share attributable to Conformis, Inc. stockholders*	$ (6.99)	$ (0.36)

*Adjusted for the 1-for-25 reverse stock split

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, 2022	2021
Common stock warrants*	—	103,646
Stock options, restricted stock awards, performance awards*	12,710	97,742
Total	12,710	201,388

*Adjusted for the 1-for-25 reverse stock split

Recent accounting pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, “Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,” which modifies the measurement approach for credit losses on financial assets measured on an amortized cost basis from an 'incurred loss' method to an 'expected loss' method. In November 2019, the FASB issued ASU 2019-11, “Codification Improvements to Topic 326, Financial Instruments – Credit Losses.” ASU 2019-11 is an accounting pronouncement that amends ASU 2016-13. The ASU 2019-11 amendment provides clarity and improves the codification to ASU 2016-13. The pronouncements are concurrently effective for fiscal years beginning after December 15, 2022 and interim periods within those fiscal years. The Company does not believe that the adoption of this ASU will have a material impact on its consolidated financial statements.

Note C—Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Total receivables	$ 10,383	$ 9,336
Allowance for doubtful accounts and returns	(610)	(257)
Accounts receivable, net	$ 9,773	$ 9,079

The beginning accounts receivable balance as of January 1, 2022 and 2021, was $9.1 million and $8.5 million, respectively. All activity within accounts receivables relate to normal operational activity from the period. Accounts receivable included unbilled receivable of $1.4 million and $1.1 million for the years ended December 31, 2022 and 2021. Write-offs related to accounts receivable were approximately $50,000 and $78,000, for the years ended December 31, 2022 and 2021, respectively.

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

	December 31, 2022	December 31, 2021
Beginning balance	$ (257)	$ (290)
Provision for bad debts on trade receivables	(396)	(48)
Other allowances	(7)	3
Accounts receivable write-offs	50	78
Ending balance	$ (610)	$ (257)

Note D—Inventories

Inventories consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Raw Material	$ 9,699	$ 6,109
Work in process	2,118	3,187
Finished goods	7,093	5,908
Total Inventories	$ 18,910	$ 15,204

Note E—Property and Equipment

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

	Estimated Useful Life (Years)	December 31, 2022	December 31, 2021
Equipment	5-7	$ 20,490	$ 20,091
Furniture and fixtures	5-7	765	873
Computer and software	3	11,037	10,540
Leasehold improvements	3-7	2,295	2,243
Reusable instruments	5	7,147	6,272
Molding and Tooling	5	489	379
Total property and equipment		42,223	40,398
Accumulated depreciation		(34,069)	(30,130)
Property and equipment, net		$ 8,154	$ 10,268

Depreciation expense related to property and equipment was $4.0 million and $4.3 million for the years ended December 31, 2022 and 2021, respectively. During the years ended December 31, 2022 and 2021, the Company did not recognize an impairment charge.

Note F—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Accrued employee compensation	$ 4,279	$ 4,701
Accrued legal expense	397	2,140
Accrued vendor charges	903	462
Accrued revenue share expense	791	824
Accrued clinical trial expense	342	335
Deferred revenue	215	—
Accrued other	1,051	1,114
	$ 7,978	$ 9,576

Note G—Leases

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-five 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.

On May 11, 2021, the Company executed an amendment to extend the term of the Wilmington lease through September 30, 2027.

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, 2022, 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 $1.8 million and $1.7 million for the years ended December 31, 2022 and 2021, respectively. The components of lease expense and related cash flows were as follows (in thousands):

	December 31, 2022	December 31, 2021
Rent expense	$ 1,940	$ 1,863
Variable lease cost [(1)]	362	426
	$ 2,302	$ 2,289

(1) Variable operating lease expenses consist primarily of common area maintenance and real estate taxes for the years ended December 31, 2022 and 2021.

As of December 31, 2022, the remaining weighted-average lease term of the operating leases was 3.87 years and the weighted-average discount rate was 6.0%.

The future minimum rental payments under these agreements as of December 31, 2022 were as follows (in thousands):

Year		Minimum Lease Payments
2022		—
2023		2,075
2024		2,126
2025		1,872
2026		971
2027		740
Total lease payments	$	7,784
Present value adjustment		(849)
Present value of lease liabilities	$	6,935

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 0.10% 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 $2.2 million during the year ended December 31, 2022, representing 3.8% of product revenue and $2.2 million during the year ended December 31, 2021, representing 3.7% 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 and research and development. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual at December 31, 2022 or December 31, 2021.

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. In the case of matters below in which we are a defendant, adverse outcomes 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.

Settlement and License Agreement with Medacta

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 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. On January 21, 2021, Medacta International SA filed a partial motion to dismiss; on February 16, 2021, the Company filed its opposition to the motion; and on March 2, 2021, Medacta International SA filed its reply. On March 4, 2021, the court issued its opinion on claim construction, ruling in the Company's favor on the construction of all of the disputed terms. On June 3, 2022, the court denied Medacta International SA's motion to dismiss. On September 8, 2022, the parties notified the court that an agreement in principle to settle the case had been reached. The trial schedule and case deadlines were canceled, pending the parties' preparation of and agreement to a definitive settlement agreement.

On October 20, 2021, the Company filed a lawsuit against Medacta Germany GmbH and Medacta International SA (together, "Medacta Europe") in the Regional Court of D✔sseldorf ("German Court"). We are seeking damages for Medacta Europe's infringement of one of our German patents related to patient-specific instrument and implant systems through Medacta Europe's sales of multiple lines of PSI, as well as the implant components used in conjunction with them, in Germany. The accused product lines include Medacta Europe's patient-specific instrument and implant systems for knee, hip, and shoulder replacement procedures. Medacta Europe filed its statement of defense on January 31, 2022. The Company filed its reply to Medacta's statement of defense on April 28, 2022. As of July 28, 2022, the Company delivered security deposits in the amount of EUR 146,000 to the German Court in order to maintain the action. On September 1, 2022, an oral hearing on infringement and liability was held. On September 9, 2022, the parties notified the court that an agreement in principle to settle the case had been reached, and the issuance of further rulings by the court was delayed, pending the parties' preparation of and agreement to a definitive settlement agreement.

On November 8, 2022, the Company entered into a non-exclusive, fully paid up, worldwide settlement and license agreement with Medacta, resolving the matters described in the two preceding paragraphs. Under the terms of this agreement, the Company granted a perpetual, irrevocable, non-exclusive license to Medacta to use patient-specific instrument technology covered by the Company's patents and patent applications with off-the-shelf implants for the knee and shoulder. This license does not extend to patient-specific implants. This license agreement provided for a single lump-sum payment by Medacta to the Company upon entering into the license agreement, which was paid in the fourth quarter of 2022.

Litigation with Osteoplastics

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. 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. Trial is currently set to begin on July 24, 2023.

Settlement and License Agreement with Wright Medical and Stryker

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 seeking damages for Wright Medical's infringement of certain of the Company's patents related to patient-specific instrument and implant systems. The complaint alleged that Wright Medical's multiple lines of patient-specific shoulder instruments, as well

as the implant components used in conjunction with them, infringed four of the Company's patents. The accused product lines included 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 infringed the patents asserted by the Company. Wright Medical's answer also alleged the affirmative defense that the Company's asserted patents are invalid.

On June 30, 2021, the Company reached a settlement and license agreement (the "Settlement and License Agreement") with Stryker Corporation ("Stryker") and Wright Medical (collectively, the "Stryker Parties"), pursuant to which the parties agreed to terms for resolving the outstanding patent infringement lawsuit described in the preceding paragraph. Wright Medical was acquired by Stryker in November 2020, subsequent to the Company's commencement of the lawsuit. In consideration of the non-exclusive license to certain of the Company's patents, releases, covenants and other immunities granted by the Company to the Stryker Parties, the Stryker Parties were required to make a one-time payment to the Company of $15.0 million no later than October 15, 2021. The Company recognized revenue of $15.0 million during the quarter ended June 30, 2021 and payment in the same amount was received from the Stryker Parties on October 15, 2021.

Litigation against DePuy

On April 30, 2021, the Company filed a lawsuit against DePuy Synthes, Inc., DePuy Synthes Products, Inc., and DePuy Synthes Sales, Inc. (collectively, "DePuy") in the United States District Court for the District of Delaware, seeking damages for DePuy's infringement of certain of the Company's patents related to patient-specific instrument and implant systems. The complaint alleges that DePuy's multiple lines of PSI, as well as the implant components used in conjunction with them, infringe seven of the Company's patents. The accused product lines include DePuy's patient-specific instrument and implant systems for knee and shoulder replacement procedures. On October 25, 2021, DePuy filed a partial motion to dismiss. On November 15, 2021, the Company filed an amended complaint. On December 6, 2021, DePuy filed a second partial motion to dismiss. The Company opposed the partial motion to dismiss on December 20, 2021, and DePuy filed a reply in support of its partial motion to dismiss on December 27, 2021. On February 14, 2022, the court denied DePuy's partial motion to dismiss. On February 28, 2022, DePuy filed its answer to the Company's amended complaint, denying that its patient-specific instrument and implant systems infringe the patents asserted by the Company. Discovery in the lawsuit is ongoing.

Litigation against Exactech

On June 3, 2021, the Company filed a lawsuit against Exactech, Inc. ("Exactech") in the United States District Court for the Middle District of Florida seeking damages for Exactech's infringement of certain of the Company's patents related to patient-specific instrument and implant systems. The complaint alleges that Exactech's line of patient-specific instruments for use with its ankle implant systems, as well as the ankle implant components used in conjunction with them, infringe five of the Company's patents. Discovery in the lawsuit is ongoing.

Litigation against Bodycad Laboratories

On June 3, 2021, the Company filed a lawsuit against Bodycad Laboratories, Inc., Bodycad USA Corp. (together, "Bodycad"), and Exactech (collectively, "Defendants"), in the United States District Court for the Middle District of Florida seeking damages for Defendants' infringement of certain of the Company's patents related to patient-specific instrument and implant systems. The complaint alleges that Defendants' line of patient-specific surgical systems for unicondylar knee replacement surgery and Bodycad's line of patient-specific surgical systems for knee osteotomy surgery infringe six of the Company's patents. On August 2, 2021, Exactech filed its answer to the complaint, denying that it infringed our asserted patents and also alleging that our asserted patents are invalid. On August 20, 2021, Bodycad filed a motion to dismiss and for a more definite statement. On September 10, 2021, the Company filed an amended complaint that continued to accuse the same products of infringing six of the Company's patents. On September 24, 2021, Defendants filed a motion to dismiss, and the Company opposed the motion to dismiss on October 15, 2021. On March 30, 2022, the court denied Defendants motion to dismiss. On February 9, 2023, the parties entered into a settlement and license agreement that resolves the patent infringement dispute filed by the Company in June of 2021. The parties agreed to an undisclosed amount for the dismissal of all patent litigation between the companies along with a release and license to certain Company patents related to patient-specific instrumentation and knee implants.

Litigation against Aetna

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 violated its duties under state and federal law, including the Employee Retirement Income Security Act. On March 31, 2021, the district court dismissed the Company’s claims against Aetna, but allowed the individual plaintiff’s claims to survive. The individual plaintiff settled his claims against Aetna in October 2021 and the Company subsequently filed a notice of appeal on April 15, 2022. Aetna filed its response to our appeal brief on June 15, 2022 and the appeals court heard oral arguments from the parties on the appeal briefs on November 8, 2022.

On January 23, 2023, the United States Court of Appeals for the First Circuit revived our trade libel claims against Aetna, finding that Aetna’s policy claims that our knee implants are “experimental” and “investigational” can plausibly be considered actionable product disparagement, and that the district court had erred in dismissing these claims. The court found that we have plausibly claimed that Aetna's policy decision caused orthopedic surgeons to stop prescribing its knee replacement implants. The court also revived our related claims for unfair trade practice and interference with advantageous relations. We intend to continue pursuing these claims against Aetna, and expect to incur additional legal expenses in 2023 (and potentially thereafter) in connection with doing so. We are seeking an award of monetary damages and equitable relief. We are not presently able to predict the ultimate outcome of this matter or to reasonably estimate a range of potential damages we may be awarded, if successful.

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, 2022	December 31, 2021
MidCap, Term Loan	21,000	21,000
Less unamortized debt issuance costs	(437)	(645)
Long-term debt, less debt issuance costs	$ 20,563	$ 20,355

Principal payments due as of December 31, 2022 consisted of the following (in thousands):

	Principal Payment
2023	—
2024	1,750
2025	10,500
2026	8,750
Total	$ 21,000

MidCap Term Loan

On November 22, 2021, the Company and its subsidiary, ImaTx, Inc., entered into the New Credit Agreement with MidCap, as agent, and certain lender parties thereto. The New Credit Agreement provides for a five-year, $21 million secured Term Facility. The New Credit Agreement refinanced and replaced the prior secured loan agreement with Innovatus that the Company entered into in June 2019 (the “2019 Secured Loan Agreement”), which agreement has been terminated. The full amount of the $21 million Term Facility was borrowed on the date of

entering into the New Credit Agreement, and the Company used these proceeds to repay all outstanding obligations under the 2019 Secured Loan Agreement.

The New Credit Agreement has a maturity date of November 1, 2026 and requires interest only payments through October 31, 2024, and thereafter, 24 monthly payments of principal and interest resulting in the Term Facility being fully paid by the maturity date. Interest is payable monthly in arrears at a rate of 5.7% per annum plus one month LIBOR subject to a LIBOR floor of 1%. In addition to the interest charged on the Term Facility, the Company is also obligated to pay certain fees, including an origination fee of 0.5% of the term loan due at closing and a final payment fee of 4.0% of the term loan at the time of final payment. On August 1, 2022, the Company entered into a New Credit Agreement, which replaced references to the LIBOR rate within the existing agreement, with the SOFR interest rate, such that interest will be payable monthly in arrears at a rate of 5.7% per annum plus one month SOFR subject to a SOFR floor of 1%. All other terms under the New Credit agreement remain the same.

The obligation of the Company with respect to the New Credit Agreement are secured by a security interest over substantially all of the personal property assets of the Company, including accounts receivable, deposit accounts, intellectual property, investment property, inventory, equipment and equity interests in its subsidiaries.The New Credit Agreement contains customary affirmative and negative covenants, including limitations on our ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, pay subordinated indebtedness and enter into affiliate transactions. In addition, the New Credit Agreement contains a minimum liquidity covenant requiring the Company to maintain unrestricted cash and cash equivalents in excess of $4.0 million. The New Credit Agreement also includes events of default customary for facilities of this type and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Term Facility may be accelerated. As of December 31, 2022, the Company was not in breach of covenants under the New Credit Agreement.

The prepayment of the debt was accounted for as a debt extinguishment and the Company incurred a loss on the extinguishment of $1.1 million. This amount consisted of final payment fee, prepayment penalty and the write-off of unamortized debt issuance costs. The loss on extinguishment of debt was recognized as interest expense within the consolidated statement of operations during the year ended December 31, 2021.

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 was a fixed rate of 1% per annum. The Company was required to make one payment of all outstanding principal plus all accrued unpaid interest on April 9, 2022 (the “Maturity Date”). The Company was required to 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. According to the terms of the PPP, all or a portion of the loan as well as any accrued interest was eligible to be fully forgiven if the funds were used for payroll costs, 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 accounted 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.

The Company submitted the loan forgiveness application to the lender on December 11, 2020. On June 30, 2021, the Company received notification through its lender that the SBA had rendered a final decision regarding its review of the PPP loan forgiveness application, fully approving the loan forgiveness application as of June 28, 2021. The Company accounted for the forgiveness of the PPP Note in accordance with ASC 405-20-40-1 and ASC 470-50-40-2, where the liability was derecognized from the balance sheet upon formal forgiveness of the loan. The resulting gain on forgiveness was measured based on the net carrying value of the PPP Note, which includes accrued interest and deferred financing costs. The Company recorded a gain on forgiveness of PPP loan of $4.8 million within Other income and expenses on the consolidated statement of operations during the quarter ended June 30, 2021.

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.

On March 30, 2021, the Company's board of directors adopted a resolution approving a Certificate of Amendment to the Company's Restated Certificate of Incorporation to increase the Company's number of authorized shares of Common Stock from 200,000,000 to 300,000,000 (the "Certificate of Amendment"). The Company's stockholders approved the Certificate of Amendment at the 2021 Annual Meeting. The total number of the Company's authorized common stock was decreased to 20,000,000 after giving effect to the Reverse Stock Split.

Reverse Stock Split

At the Company's 2022 Annual Meeting of Stockholders, the Company's stockholders approved a proposed amendment to the Company's Restated Certificate of Incorporation to effect a reverse stock split of all of the Company's outstanding shares of common stock by one of several fixed ratios between 1-for-2 and 1-for-10 and to correspondingly decrease the number of authorized shares of the Company's common stock as disclosed in the Company's proxy statement for the 2022 Annual Meeting of Stockholders. The reverse stock split was proposed to address the Company's current non-compliance with Nasdaq's $1.00 per share minimum bid price requirement.

On October 26, 2022, the Company held a Special Meeting of Stockholders and the Company's stockholders approved an additional proposed amendment to the Company's Restated Certificate of Incorporation to effect a reverse stock split of all of the Company's outstanding shares of common stock by one of three fixed ratios, 1-for-15, 1-for-20 and 1-for-25, and to correspondingly adjust the number of authorized shares of the Company's common stock by the approved ratio, 1-for-9, 1-for-12 and 1-for-15, respectively (the "Updated Reverse Stock Split Proposal"), as disclosed in the Company's proxy statement for the October 26, 2022 Special Meeting of Stockholders. The Updated Reverse Stock Split Proposal amendment was proposed to address the Company's current non-compliance with Nasdaq's $1.00 per share minimum bid price requirement.

The Company's Board of Directors determined to proceed with implementing the 1-for-25 reverse stock split that was approved by shareholder on October 26, 2022, and such 1-for-25 reverse stock split was implemented in November 2022 (the "Reverse Stock Split") . As a result of the Reverse Stock Split, each of the holders of the Company's Common Stock received one (1) new share of Common Stock for every twenty-five (25) shares such shareholder held immediately prior. No fractional shares were issued as a result of the Reverse Stock Split. Any fractional shares that would have otherwise resulted from the Reverse Stock Split were rounded up to the next whole number of shares. The Reverse Stock Split also affected the Company's outstanding stock options and warrants and resulted in the shares underlying such instruments being reduced and the exercise price being increased proportionately to the Reverse Stock Split ratio.

All share and per share information was retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated. The total number of the Company's authorized shares of preferred stock was not affected by the foregoing. However, the total number of the Company's authorized common stock was decreased to 20,000,000. In connection with the Reverse Stock Split, there was no change in the par value per share of $0.00001.

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, 2022 and December 31, 2021.

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.

"At-the-market” program

On March 23, 2020, the Company filed a shelf registration statement on Form S-3 (the "Shelf Registration Statement"), which was declared effective by the SEC on August 5, 2020. Under the 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. Under the Sales Agreement, 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 have provided Cowen with customary indemnification rights. Any shares of Common Stock offered pursuant to the Sales Agreement will be offered and sold pursuant to the 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 the date hereof, the Company has 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 76,879 shares of common stock (adjusted for the 1-for-25 reverse stock split) 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 14,177 shares (adjusted for the 1-for-25 reverse stock split) to LPC. The Company had 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 controlled the timing of any sales to LPC and LPC was 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 were no upper limits to the price per share LPC would 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 was to 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 was not 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 were associated with the Stock Purchase Agreement and LPC 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 expired on January 1, 2022.

2021 common stock offering

On February 17, 2021, the Company closed an offering of its common stock under the Shelf Registration Statement and issued and sold 3,238,095 shares of its common stock at a public offering price of $26.25 per share (adjusted for the 1-for-25 reverse stock split), 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.

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) 340,483 shares of its common stock and accompanying warrants to purchase up to 340,483 shares of common stock and (ii) pre-funded warrants to purchase up to 379,718 shares of common stock and accompanying warrants to purchase up to 379,718 shares of common stock in a registered direct offering (adjusted for the 1-for-25 reverse stock split) 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 $23.95 per unit.

The pre-funded warrants became exercisable immediately upon issuance, have an exercise price of $0.0025 per share and were exercisable until all of the pre-funded warrants were exercised in full. As of March 31, 2021, all pre-funded warrants were exercised. The warrants became exercisable immediately upon issuance, have an exercise price of $21.87 per share (adjusted for the 1-for-25 reverse stock split), 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 379,718 pre-funded common stock warrants with an exercise price of $0.0025 per share and an additional 720,201 common stock warrants with an exercise price of $21.87 per share (adjusted for the 1-for-25 reverse stock split). All of the warrants are exercisable for one share of common stock and are exercisable immediately. As of December 31, 2022, approximately 240,000 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 $21.87 and share price of $20.83 per share based on the trading price of the Company's common stock (adjusted for the 1-for-25 reverse stock split).

Warrants to purchase 480,837 shares of common stock were outstanding as of December 31, 2022 and December 31, 2021. Outstanding common stock warrants are currently exercisable with varying exercise expiration dates from 2024 through 2025. At December 31, 2022 and December 31, 2021, the weighted average warrant exercise price per share for common stock and the weighted average contractual life was as follows:

	Number of Common Stock Warrants *	Weighted Average Exercise Price Per Share*	Weighted Average Remaining Contractual Life	Number of Warrants Exercisable*	Weighted Average Price Per Share*
Outstanding December 31, 2021	480,837	$ 22.22	3.73	480,837	$ 22.22
Granted	—	$ —	—	—	$ —
Exercised	—	—	—	—	—
Cancelled/expired	—	—	—	—	—
Outstanding December 31, 2022	480,837	$ 22.22	2.73	480,837	$ 22.22

*Adjusted for the 1-for-25 reverse stock split

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, 2022, an additional 120,000 shares of the Company's common stock were added to the 2015 Plan under the terms of this provision (adjusted for the 1-for-25 reverse stock split), and at the 2021 Annual Meeting of Stockholders on May 24, 2021, the Company' Stockholders approved a First Amendment to the 2015 Plan to increase by 240,000 (adjusted for the 1-for-25 reverse stock split), the maximum number of shares of common stock available for issuance under the 2015 Plan ("Plan Amendment"). As of December 31, 2022, 191,526 shares of common stock were available for future issuance under the 2015 Plan (adjusted for the 1-for-25 reverse stock split).

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, 2022, 87,958 shares of common stock were available for future issuance under the 2019 Sales Team Plan (adjusted for the 1-for-25 reverse stock split).

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, 2020	70,081	$ 127.77	$ —
Granted	9,599	25.56	—
Expired	(8,583)	131.48	—
Cancelled/Forfeited	(4,599)	33.00	—
Outstanding December 31, 2021	66,498	$ 119.01	$ —
Granted	130,084	11.83	—
Expired	(17,316)	86.29	—
Cancelled/Forfeited	(3,483)	26.15	—
Outstanding December 31, 2022	175,783	$ 44.76	$ —
Total vested and exercisable	44,240	$ 142.25	$ —

*Adjusted for the 1-for-25 reverse stock split

The total fair value of stock options that vested during the year ended December 31, 2022 was $0.1 million. The weighted average remaining contractual term for the total stock options outstanding was 8.06 years at December 31, 2022. The weighted average remaining contractual term for the total stock options vested and exercisable was 4.30 years at December 31, 2022.

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

	Number of Shares*	Weighted Average Fair Value*
Unvested December 31, 2020	251,085	$ 29.41
Granted	164,822	23.29
Vested	(103,611)	29.35
Forfeited	(26,928)	23.92
Unvested December 31, 2021	285,368	$ 26.41
Granted	127,332	10.51
Vested	(104,100)	27.38
Forfeited	(70,651)	22.06
Unvested December 31, 2022	237,949	$ 18.77

*Adjusted for the 1-for-25 reverse stock split

The total fair value of restricted common stock awards that vested during the year ended December 31, 2022 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 5,000 shares of the Company's common stock with an exercise price per share equal to $24.50 and 5,000 restricted stock units (adjusted for the 1-for-25 reverse stock split). 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 November 2021, the Company granted inducement awards outside of the 2015 Plan and 2019 Sales Team Plan to the Company's Vice President, Marketing in the form of 6,000 restricted stock units (adjusted for the 1-for-25 reverse stock split). 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).

In March 2022, the Company granted inducement awards outside of the 2015 Plan and 2019 Sales Team Plan to the Company's Chief Legal Officer and Corporate Secretary in the form of an option to purchase 18,000 shares of the Company's common stock with an exercise price per share equal to $15.25 and 18,000 restricted stock units (adjusted for the 1-for-25 reverse stock split). The option and restricted stock unit awards were granted as inducements material to her commencement of employment with the Company in accordance with NASDAQ Listing Rule 5635(c)(4).

In April 2022, the Company granted inducement awards outside of the 2015 Plan and 2019 Sales Team Plan to the Company's Chief Operating Officer in the form of an option to purchase 17,000 shares of the Company's common stock with an exercise price per share equal to $16.00 and 17,000 restricted stock units (adjusted for the 1-for-25 reverse stock split). 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).

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 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 $9.18 and $17.91 for the year ended December 31, 2022 and 2021, 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,	
	2022	2021
Risk-free interest rate	2.61%	—%
Expected term (in years)	6.72	0
Dividend yield	—%	—%
Expected volatility	89.21%	—%

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. Prior to July 1, 2021, the Company estimated volatility using the historical volatilities of similar public entities. Beginning July 1, 2021, the Company estimates volatility based on the historical volatility of the Company's stock.

Forfeitures. The Company recognizes forfeitures as they occur.

Stock-based compensation expense was $2.1 million and $3.8 million for the years ended December 31, 2022 and 2021, 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,	
	2022	2021
Cost of revenue	$ 14	$ 75
Sales and marketing	364	708
Research and development	272	582
General and administrative	1,482	2,450
	$ 2,132	$ 3,815

At December 31, 2022, the Company had $1.1 million of total unrecognized compensation expense for options that will be recognized over a weighted average period of 4.39 years. At December 31, 2022, the Company had $3.8 million of total unrecognized compensation expense for restricted awards recognized over a weighted average period of 2.08 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, 2022 and 2021 includes the following components (in thousands):

	Years ended December 31,	
	2022	2021
Loss before income taxes:		
U.S.	$ (49,018)	$ (219)
Non-U.S.	(1,478)	(2,103)
	$ (50,496)	$ (2,322)

Significant components of the (benefit) provision for income taxes for the years ended December 31, 2022 and 2021 were as follows (in thousands):

	Years ended December 31,	
	2022	2021
Current:		
Federal	$ —	$ —
State	4	33
Foreign	(27)	58
	(23)	91
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
	—	—
Total	$ (23)	$ 91

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,	
	2022	2021
Tax at U.S. statutory rate	21.00 %	21.00 %
State taxes, net of federal benefits	(0.08)	51.39
Permanent items	(1.04)	155.29
Tax credit	0.32	(14.94)
Change in valuation allowance	(20.04)	(251.92)
Foreign rate differential	0.16	4.79
Rate change	—	(7.90)
Uncertain tax positions	0.16	23.08
NQ Stock option expirations & forfeitures	—	(1.54)
Prior period true ups	—	19.46
Other	—	(2.63)
	0.48 %	(3.92)%

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,	
	2022	2021
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 31,800	$ 25,101
Foreign net operating loss carryforwards	7,509	7,458
Accrued expenses	463	444
Credits	7,774	7,776
Intangibles	1,196	1,203
Stock compensation expense	778	1,075
Lease liability	1,734	1,957
Capitalized R&D Expenses	3,681	—
Other	7,051	4,906
Total deferred tax assets	61,986	49,920
Valuation allowance	(59,952)	(47,354)
Net deferred tax assets	2,034	2,566
Deferred tax liabilities:		
Fixed assets	(517)	(751)
Right of use asset	(1,517)	(1,774)
Other	—	(41)
Net deferred tax liabilities	(2,034)	(2,566)
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 $60.0 million valuation allowance at December 31, 2022 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 $12.6 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, 2022, the Company had approximately $469.8 million of federal net operating loss carryforwards of which $378.2 million if not utilized, a portion will begin to expire in 2023 for federal tax purposes, while $91.7 million of the total will not expire, and approximately $273.6 million of state net operating loss carryforwards that if not utilized, will continue to expire at various dates starting in 2023 for state tax purposes, while $12.2 million of the total will not expire. The Company also has federal and state tax credits of $5.8 million and $2.4 million, which begin to expire in 2022 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, 2022. The limitations may reduce the amount of federal and state NOLs and credits of $469.8 million and $273.6 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 $36.7 million as of December 31, 2022, 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.

The Company has adopted the accounting guidance related to uncertainty in income taxes. The total liability for unrecognized income tax benefits was approximately $3.8 million and $3.6 million as of December 31, 2022 and 2021, respectively. Of the total liability at December 31, 2022 and 2021, $3.5 million and $3.1 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 $0.1 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.

	Years ended December 31,	
	2022	2021
Unrecognized tax benefits beginning of year	$ 3,558	$ 4,094
Gross change for current year positions	488	633
Increase for prior period positions	9	23
Decrease for prior period positions	—	—
Decrease due to statute limitations	(245)	(1,192)
Unrecognized tax benefits end of the year	$ 3,810	$ 3,558

As of December 31, 2022, 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. On January 17, 2023, the Company was informed that the German authorities had preliminary completed a transfer pricing audit, resulting in the reduction of NOLs from 2017-2019. The Company is still assessing these findings and due to the subsequent nature of the event, the Company will record the impacts of these events in the first quarter of 2023.

At December 31, 2022, 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 and distributors managed by that respective country. Net property and equipment are based upon physical location of the assets.

Geographic information consisted of the following (in thousands):

	Years Ended December 31,	
	2022	2021
Product Revenue		
United States	$ 50,527	$ 50,990
Germany	3,215	5,422
Rest of World	4,083	1,906
	$ 57,825	$ 58,318

	December 31,	
	2022	2021
Property and equipment, net		
United States	$ 8,065	$ 10,131
Germany	29	43
Rest of World	$ 60	$ 94
	$ 8,154	$ 10,268

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 100% 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 $0.6 million to the plan during the year ended December 31, 2022 and approximately $0.5 million during the year ended December 31, 2021.

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, 2022. 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, 2022, 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, 2022. 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, 2022, 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, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

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 2023 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 2023 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 2023 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 2023 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 2023 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 2023 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 2023 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

The Public Company Accounting Oversight Board ID Number of the audit firm or branch that provided the opinion: 248

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	Certificate of Amendment to Restated Certificate of Incorporation of Conformis, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed on May 27, 2001)
3.4	Certificate of Amendment to Restated Certificate of Incorporation of Conformis, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed on November 9, 2022)
3.5	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^	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)
10.2^	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)
10.3^	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)
10.4^	Conformis, Inc. 2015 Stock Incentive Plan, as Amended by Amendment No. 1 thereto (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed on May 27, 2021)
10.5^	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)
10.6^	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)
10.7^	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)
10.8^	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)
10.9^	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)
10.10^	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)
10.11^	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)
10.12	Form of Inducement Incentive Grant Agreement (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form 8-K filed on March 14, 2022)

10.13	Form of Non-Statutory Stock Option Grant Agreement (incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form 8-K filed on March 14, 2022)
10.14^	Form of Performance-Based Restricted Stock Unit Agreement under 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2021 filed on August 4, 2021)
10.15	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)
10.16	Sales Agreement, dated August 5, 2020, by and between Conformis, Inc. and Cowen and Company, LLC. (incorporated herein by reference to the Registrant's Registration Statement on Form S-8 filed on August 6, 2020)
10.17	Form of Common Stock Warrant Agreement - September 2020 Offering (incorporated herein by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form 8-K filed on September 24, 2020)
10.18	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)
10.19^	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)
10.20	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)
10.21	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)
10.22	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)
10.23	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)
10.24†	License Agreement, dated as of April 13, 2015, between the Registrant and MicroPort Orthopedics Inc. (incorporated by reference to Exhibit 10.32 to the Registrant's registration statement on Form S-1/A (File No. 333-204384) filed on June 11, 2015)
10.25	License Agreement, dated as of April 13, 2015, between the Registrant and each of Wright Medical Group, Inc. and Wright Medical Technology, Inc. (incorporated by reference to Exhibit 10.33 to the Registrant's registration statement on Form S-1/A (File No. 333-204384) filed on June 11, 2015)
10.26†	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)
10.27†	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)
10.28†	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)
10.29†	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)
10.30†	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)
10.31	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)

10.32	Credit and Security Agreement (Term Loan), dated as of November 22, 2021, among Conformis, Inc., ImaTx, Inc., the lenders from time to time party thereto, and MidCap Financial Trust, as agent (incorporated by reference to Exhibit 10.1 to Registrant's current report on Form 8-K filed on November 23, 2021)
10.33*	First Amendment to Credit and Security Agreement (Term Loan), dated as of August 1, 2022, among Conformis, Inc., ImaTx, Inc., the lenders from time to time party thereto, and MidCap Financial Trust, as agent.
10.34^	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)
10.35^	Amendment to Employment Agreement dated September 14, 2017, by and between Conformis, Inc. and Mark Augusti, its President and Chief Executive Officer (incorporated herein by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2017, filed on November 9, 2017)
10.36^	Second Amendment to Amended and Restated Employment Agreement dated July 31, 2018, by and between Conformis, Inc. and Mark Augusti, its Chief Executive Officer (incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2018, filed on August 2, 2018)
10.37^	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)
10.38^	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)
10.39^	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)
10.40^	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)
10.41	Employment Agreement, effective as of March 14, 2022, by and between Conformis, Inc. and Denise Pedulla, its Chief Legal Officer and Corporate Secretary (incorporated herein by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on March 14, 2022)
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

* 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: 3/1/2023

CONFORMIS, INC.

By: /s/Mark A. Augusti

Mark A. Augusti
President and Chief Executive Officer

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

Signature	Title	Date
/s/Mark A. Augusti Mark A. Augusti	President and Chief Executive Officer (Principal Executive Officer) and Director	3/1/2023
/s/Robert Howe Robert Howe	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	3/1/2023
/s/Kenneth Fallon III Kenneth Fallon III	Chairman of the Board of Directors	3/1/2023
/s/Philip W. Johnston Philip W. Johnston	Director	3/1/2023
/s/Carrie Bienkowski Carrie Bienkowski	Director	3/1/2023
/s/Bradley Langdale Bradley Langdale	Director	3/1/2023
/s/Gary Fischetti Gary Fischetti	Director	3/1/2023
/s/Michael Milligan Michael Milligan	Director	3/1/2023

FIRST AMENDMENT TO CREDIT AND SECURITY AGREEMENT

This FIRST AMENDMENT TO CREDIT AND SECURITY AGREEMENT (this "**Agreement**") is made as of this 1st day of August, 2022, by and among **CONFORMIS, INC.**, a Delaware corporation, an **IMATX, INC.**, a California corporation, as Borrowers (each individually and, collectively in the singular, "**Borrower**"), **MIDCAP FINANCIAL TRUST**, as Agent for Lenders (in such capacity and together with its permitted successors and assigns, the "**Agent**"), and the financial institutions or other entities from time to time parties to the Credit Agreement referenced below, each as a Lender.

RECITALS

A. Agent, Lenders, and Borrower have entered into that certain Credit and Security Agreement (Term Loan), dated as of November 22, 2021 (as amended, restated, supplemented or otherwise modified prior to the date hereof, the "**Existing Credit Agreement**" and as the same is amended hereby and as it may be further amended, restated, supplemented or otherwise modified from time to time, the "**Credit Agreement**"), pursuant to which the Lenders have agreed to make certain advances of money and to extend certain financial accommodations to Borrower in the amounts and manner set forth in the Credit Agreement.

B. Borrower, Agent and Lenders have agreed to amend certain provisions of the Existing Credit Agreement as set forth herein, in accordance with the terms and subject to the conditions set forth herein, to, among other things, amend certain other provisions of the Existing Credit Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing, the terms and conditions set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Agent, Lenders party hereto and Borrower hereby agree as follows:

1. **Recitals; Construction**. This Agreement shall constitute a Financing Document and the Recitals and each reference to the Credit Agreement, unless otherwise expressly noted, will be deemed to reference the Credit Agreement as modified hereby. The Recitals set forth above shall be construed as part of this Agreement as if set forth fully in the body of this Agreement and capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Credit Agreement (including those capitalized terms used in the Recitals hereto).

2. **Amendments to Credit Agreement**.

(a) **Section 1.1 (Certain Defined Terms)**. The following terms and their respective definitions set forth in Section 1.1 of the Existing Credit Agreement are hereby amended in their entirety and replaced with the following:

"**Business Day**" means any day except a Saturday, Sunday or other day on which either the New York Stock Exchange is closed, or on which commercial banks in New York, New York are authorized by Law to close; provided, however, that when used in the context of a SOFR Loan, the term "Business Day" shall also exclude any day that is not also a SOFR Business Day.

(b) **Section 1.1 (Certain Defined Terms)**. The following new defined terms are hereby inserted in Section 1.1 of the Existing Credit Agreement in the appropriate alphabetical order:

"**Available Tenor**" means, as of any date of determination with respect to the then-current Benchmark, (a) if such Benchmark is a term rate, any tenor for such Benchmark (or component

thereof) that is or may be used for determining the length of an interest period pursuant to this Agreement or (b) otherwise, any payment period for interest calculated with reference to such Benchmark (or component thereof) that is or may be used for determining any frequency of making payments of interest calculated with reference to such Benchmark pursuant to this Agreement, in each case, as of such date and not including, for the avoidance of doubt, any tenor for such Benchmark that is then-removed from the definition of "Applicable Interest Period" or similar term pursuant to Section 2.2(c).

"**Benchmark**" means, initially, Term SOFR; provided that if a Benchmark Transition Event and its related Benchmark Replacement Date have occurred with respect to Term SOFR or the then- current Benchmark, then "Benchmark" means the applicable Benchmark Replacement to the extent that such Benchmark Replacement has replaced such prior benchmark rate pursuant to Section 2.2(c).

"**Benchmark Replacement**" means, with respect to any Benchmark Transition Event, the sum of: (a) the alternate benchmark rate that has been selected by Agent giving due consideration to
(i) any selection or recommendation of a replacement benchmark rate or the mechanism for determining such a rate by the Relevant Governmental Body or (ii) any evolving or then- prevailing market convention for determining a benchmark rate as a replacement to the then- current Benchmark for Dollar-denominated syndicated credit facilities at such time and (b) the related Benchmark Replacement Adjustment; provided that, if such Benchmark Replacement as so determined would be less than the Floor, such Benchmark Replacement will be deemed to be the Floor for the purposes of this Agreement and the other Financing Documents.

"**Benchmark Replacement Adjustment**" means, with respect to any replacement of the then- current Benchmark with an Unadjusted Benchmark Replacement for any applicable Available Tenor, the spread adjustment, or method for calculating or determining such spread adjustment (which may be a positive or negative value or zero) that has been selected by Agent giving due consideration to any selection or recommendation by the Relevant Governmental Body, or any evolving or then-prevailing market convention at such time, for determining a spread adjustment, or method for calculating or determining such spread adjustment, for such type of replacement for
U.S. dollar-denominated syndicated credit facilities at such time.

"**Benchmark Replacement Date**" means the earlier to occur of the following events with respect to the then-current Benchmark: (a) in the case of clause (a) or (b) of the definition of "Benchmark Transition Event", the later of (i) the date of the public statement or publication of information referenced therein and (ii) the date on which the administrator of such Benchmark (or the published component used in the calculation thereof) permanently or indefinitely ceases to provide all Available Tenors of such Benchmark (or such component thereof); or (b) in the case of clause (c) of the definition of "Benchmark Transition Event", the first date on which such Benchmark (or the published component used in the calculation thereof) has been determined and announced by the regulatory supervisor for the administrator of such Benchmark (or such component thereof) to be no longer representative; provided, that such non-representativeness will be determined by reference to the most recent statement or publication referenced in such clause (c) even if any Available Tenor of such Benchmark (or such component thereof) continues to be provided on such date. For the avoidance of doubt, the "Benchmark Replacement Date" will be deemed to have occurred in the case of clause (a) or (b) with respect to any Benchmark upon the occurrence of the applicable event or events set forth therein with respect to all then- current Available Tenors of such Benchmark (or the published component used in the calculation thereof).

"**Benchmark Transition Event**" means the occurrence of one or more of the following events with respect to the then-current Benchmark: (a) a public statement or publication of information by or on behalf of the administrator of such Benchmark (or the published component used in the calculation thereof) announcing that such administrator has ceased or will cease to provide all Available Tenors of such Benchmark (or such component thereof), permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark (or such component thereof);
(b) a public statement or publication of information by the regulatory supervisor for the administrator of such Benchmark (or the published component used in the calculation thereof), the Federal Reserve Board, the Federal Reserve Bank of New York, an insolvency official or resolution authority with jurisdiction over the administrator for such Benchmark (or such component), or a court or an entity with similar insolvency or resolution authority, which states that the administrator of such Benchmark (or such component) has ceased or will cease to provide all Available Tenors of such Benchmark (or such component thereof) permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark (or such component thereof); or
(c) a public statement or publication of information by the regulatory supervisor for the administrator of such Benchmark (or the published component used in the calculation thereof) announcing that all Available Tenors of such Benchmark (or such component thereof) are no longer, or as of a specified future date will no longer be, representative. For the avoidance of doubt, a "Benchmark Transition Event" will be deemed to have occurred with respect to any Benchmark if a public statement or publication of information set forth above has occurred with respect to each then-current Available Tenor of such Benchmark (or the published component used in the calculation thereof).

"**Benchmark Transition Start Date**" means, in the case of a Benchmark Transition Event, the earlier of (a) the applicable Benchmark Replacement Date and (b) if such Benchmark Transition Event is a public statement or publication of information of a prospective event, the 90th day prior to the expected date of such event as of such public statement or publication of information (or if the expected date of such prospective event is fewer than 90 days after such statement or publication, the date of such statement or publication).

"**Benchmark Unavailability Period**" means the period (if any) (a) beginning at the time that a Benchmark Replacement Date pursuant to clauses (a) or (b) of that definition has occurred if, at such time, no Benchmark Replacement has replaced the then-current Benchmark for all purposes hereunder and under any Financing Document in accordance with Section 2.2(c) and (b) ending at the time that a Benchmark Replacement has replaced the then-current Benchmark for all purposes hereunder and under any Financing Document in accordance with Section 2.2(c).

"**Conforming Changes**" means, with respect to Term SOFR or any Benchmark Replacement, any technical, administrative or operational changes (including (a) changes to the definition of "Business Day", "Reference Time" or other definitions, (b) the addition of concepts such as "interest period", (c) changes to timing and/or frequency of determining rates, making interest payments, giving borrowing requests, prepayment, conversion or continuation notices, or length of lookback periods, (d) the applicability of Section 2.8 (Taxes; Capital Adequacy; Increased Costs; Inability to Determine Rates; Illegality) and (e) other technical, administrative or operational matters) that Agent decides may be appropriate to reflect the adoption and implementation of Term SOFR or such Benchmark Replacement and to permit the administration thereof by Agent in a manner substantially consistent with market practice (or, if Agent decides that adoption of any portion of such market practice is not administratively feasible or determines that no such market practice exists, in such other manner as Agent decides is reasonably

necessary in connection with the administration of this Agreement and the other Financing Documents).

"**Floor**" means the rate per annum of interest equal to 1.00%.

"**Reference Time**" means approximately a time substantially consistent with market practice two (2) SOFR Business Days prior to the first day of each calendar month. If by 5:00 pm (New York City time) on any interest lookback day, Term SOFR in respect of such interest lookback day has not been published on the SOFR Administrator's Website, then Term SOFR for such interest lookback day will be Term SOFR as published in respect of the first preceding SOFR Business Day for which Term SOFR was published on the SOFR Administrator's Website; provided that such first preceding SOFR Business Day is not more than three (3) SOFR Business Days prior to such interest lookback day.

"**Relevant Governmental Body**" means the Federal Reserve Board and/or the Federal Reserve Bank of New York, or a committee officially endorsed or convened by the Federal Reserve Board and/or the Federal Reserve Bank of New York or any successor thereto.

"**SOFR"** means, with respect to any SOFR Business Day, a rate per annum equal to the secured overnight financing rate for such SOFR Business Day.

"**SOFR Administrator**" means CME Group Benchmark Administration Limited (CBA) (or a successor administrator of Term SOFR selected by Agent in its reasonable discretion).

"**SOFR Administrator's Website**" means the website of the SOFR Administrator, currently at https://www.cmegroup.com/market-data/cme-group-benchmark-administration/term-sofr.html, or any successor source for Term SOFR identified by the SOFR Administrator from time to time.

"**SOFR Business Day**" means any day other than a Saturday or Sunday or a day on which the Securities Industry and Financial Markets Association recommends that the fixed income departments of its members be closed for the entire day for purposes of trading in United States government securities.

"**SOFR Interest Rate**" means, with respect to each day during which interest accrues on a Loan, the rate per annum (expressed as a percentage) equal to (a) Term SOFR for the applicable Interest Period for such day; or (b) if the then-current Benchmark has been replaced with a Benchmark Replacement pursuant to Section 2.2(c), such Benchmark Replacement for such day. Notwithstanding the foregoing, the SOFR Interest Rate shall not at any time be less the Floor.

"**SOFR Loan**" means a Loan that bears interest at a rate based on Term SOFR.

"**Term SOFR**" means the greater of (a) the forward-looking term rate for a period comparable to such Interest Period based on SOFR that is published by the SOFR Administrator and is displayed on the SOFR Administrator's Website at approximately the Reference Time for such Interest Period and (b) the Floor, in each case, plus 0.10%. Unless otherwise specified in any amendment to this Agreement entered into in accordance with Section 2.2(c), in the event that a Benchmark Replacement with respect to Term SOFR is implemented, then all references herein to Term SOFR shall be deemed references to such Benchmark Replacement.

"**Unadjusted Benchmark Replacement**" means the applicable Benchmark Replacement excluding the related Benchmark Replacement Adjustment.

(c) **Section 1.1 (Certain Defined Terms).** The following defined terms set forth in Section 1.1 of the Existing Credit Agreement are hereby deleted in their entirety: "Base LIBOR Rate", "LIBOR Rate", and "LIBOR Replacement Confirming Changes".

(d) **Section 2.1 (Loans)**. Section 2.1(a)(iv) of the Existing Credit Agreement is hereby removed in its entirety.

(e) **Section 2.2(a) (Interest)**. Section 2.2(a) of the Existing Credit Agreement is hereby amended to:

(i) add "(i)" after "Interest";

(ii) replace the reference to "LIBOR Rate" in (i) with "SOFR Interest Rate"; and

(iii) add the following new clauses (ii) and (iii):

(ii) In the event one or more of the following events occurs with respect to Term SOFR: (a) a public statement or publication of information by or on behalf of the SOFR Administrator announcing that the SOFR Administrator has ceased or will cease to provide Term SOFR for a 1-month period, permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide Term SOFR for a 1-month period; (b) a public statement or publication of information by the regulatory supervisor for the SOFR Administrator, the Federal Reserve Board, the Federal Reserve Bank of New York, an insolvency official or resolution authority with jurisdiction over the SOFR Administrator, or a court or an entity with similar insolvency or resolution authority, which states that the SOFR Administrator has ceased or will cease to provide Term SOFR for a 1-month period permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide Term SOFR for a 1-month period; or (c) a public statement or publication of information by the regulatory supervisor for the SOFR Administrator announcing that Term SOFR for a 1-month period is no longer, or as of a specified future date will no longer be, representative and Agent has provided Borrower Representative with notice of the same, any outstanding affected SOFR Loans will be deemed to have been converted to Base Rate Loans at the end of the applicable Interest Period.

(iii) In connection with Term SOFR, Agent will have the right to make Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Financing Document, any amendments implementing such Conforming Changes will become effective without any further action or consent of any other party to this Agreement or any other Financing Document. Agent will promptly notify Borrower Representative and the Lenders of the effectiveness of any Conforming Changes.

(f) **Section 2.2(c) (Reserved)**. Section 2.2(c) of the Existing Credit Agreement is hereby amended and restated as follows:

(c) Benchmark Replacement Setting; Conforming Changes.

(i) Upon the occurrence of a Benchmark Transition Event, Agent and Borrowers may amend this Agreement to replace the then-current Benchmark with a Benchmark Replacement. Any such amendment will become effective at 5:00 p.m. (New York City time) on the fifth (5th) Business Day after Agent has posted such proposed amendment to all Lenders and Borrower so long as Agent has not received, by such time, written notice of objection thereto from Lenders comprising the Required Lenders. No such replacement will occur prior to the applicable Benchmark Transition Start Date. In connection with the implementation of a Benchmark Replacement, Agent will have the right to make Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Financing Document, any amendments implementing such Conforming Changes will become effective without any further action or consent of any other party to this Agreement or any other Financing Document. Agent will promptly notify Borrower and the Lenders of the implementation of any Benchmark Replacement and the effectiveness of any Conforming Changes.

(ii) Any determination, decision or election that may be made by Agent or, if applicable, any Lender (or group of Lenders) pursuant to this Section will be conclusive and binding absent manifest error and may be made in its or their sole discretion and without consent from any other party to this Agreement or any other Financing Document, except, in each case, as expressly required pursuant to this Section. Notwithstanding anything to the contrary herein or in any other Financing Document, at any time, (a) if the then-current Benchmark is a term rate (including Term SOFR) and either (i) any tenor for such Benchmark is not displayed on a screen or other information service that publishes such rate from time to time as selected by Agent in its reasonable discretion or (ii) the regulatory supervisor for the administrator of such Benchmark has provided a public statement or publication of information announcing that any tenor for such Benchmark is or will be no longer representative, then Agent may modify the definition of "Interest Period" (or any similar or analogous definition) for any Benchmark settings at or after such time to remove such unavailable or non- representative tenor, and (b) if a tenor that was removed pursuant to clause (a) above either (i) is subsequently displayed on a screen or information service for a Benchmark or (ii) is not, or is no longer, subject to an announcement that it is or will no longer be representative for a Benchmark, then Agent may modify the definition of "Interest Period" (or any similar or analogous definition) for all Benchmark settings at or after such time to reinstate such previously removed tenor. Agent will promptly notify Borrower of the removal or reinstatement of any tenor of a Benchmark pursuant to this Section.

(iii) Upon Borrower Representative's receipt of notice of the commencement of a Benchmark Unavailability Period, any outstanding affected Loans will be deemed to have been converted into Base Rate at the end of the applicable Interest Period.

(g) **Section 2.8 (Taxes; Capital Adequacy)**. Section 2.8 of the Existing Credit Agreement is hereby amended to:

(i) amend and restate the heading of such Section to read "Taxes; Capital Adequacy; Increased Costs; Inability to Determine Rates; Illegality"; and

(ii) amend and restate clauses (g), (h) and (i), and insert new clauses (j), (k) and (l) as follows:

(g) If any Lender shall reasonably determine that the adoption or taking effect of, or any change in, any applicable Law regarding capital adequacy, in each instance, after the Closing Date, or any change after the Closing Date in the interpretation, administration or application thereof by any Governmental Authority, central bank or comparable agency charged with the interpretation, administration or application thereof, or the compliance by any Lender or any Person controlling such Lender with any request, guideline or directive regarding capital adequacy (whether or not having the force of Law) of any such Governmental Authority, central bank or comparable agency adopted or otherwise taking effect after the Closing Date, has or would have the effect of reducing the rate of return on such Lender's or such controlling Person's capital as a consequence of such Lender's obligations hereunder to a level below that which such Lender or such controlling Person could have achieved but for such adoption, taking effect, change, interpretation, administration, application or compliance (taking into consideration such Lender's or such controlling Person's policies with respect to capital adequacy) then from time to time, upon demand by such Lender (which demand shall be accompanied by a certificate setting forth the basis for such demand and a calculation of the amount thereof in reasonable detail, a copy of which shall be furnished to Agent), Borrowers shall promptly pay to such Lender such additional amount as will compensate such Lender or such controlling Person for such reduction, so long as such amounts have accrued on or after the day which is two hundred seventy (270) days prior to the date on which such Lender first made demand therefor; *provided* that notwithstanding anything in this Agreement to the contrary, (i) the Dodd- Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (ii) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to be a "change in applicable Law", regardless of the date enacted, adopted or issued.

(h) If any Lender shall reasonably determine that the adoption or taking effect of, or any change in, any applicable Law shall (i) impose, modify or deem applicable any reserve, special deposit, compulsory loan, insurance charge or similar requirement against assets of, deposits with or for the account of, or credit extended or participated in by, any Lender, (ii) subject any Lender to any tax of any kind whatsoever with respect to this Agreement, or any SOFR Loan made by it, or change the basis of taxation of payments to such Lender in respect thereof (except for Taxes covered by Section 2.8(a)-(f)); or (iii) impose on any Lender any other condition, cost or expense affecting this Agreement or SOFR Loans made by such Lender, and the result of any of the foregoing shall be to increase the cost to such Lender of making or maintaining any Loan the interest on which is determined by reference to Term SOFR (or of maintaining its obligation to make any such Loan), or to reduce the amount of any sum received or receivable by such Lender (whether of principal, interest or any other amount) then, upon request of such Lender, the Borrower will pay to such Lender such additional amount or amounts as will compensate such Lender for such additional costs incurred or reduction suffered.

(i) If any Lender requests compensation under this Section 2.8, or requires Borrower to pay any additional amount to any Lender or any Governmental Authority for

the account of any Lender pursuant to this Section 2.8, then, upon the written request of Borrower Representative, such Lender shall use reasonable efforts to designate a different lending office for funding or booking its Loans hereunder or to assign its rights and obligations hereunder (subject to the provisions of Section 11.17) to another of its offices, branches or affiliates, if, in the reasonable judgment of such Lender, such designation or assignment (i) would eliminate or materially reduce amounts payable pursuant to any such Section, as the case may be, in the future, (ii) would not subject such Lender to any unreimbursed cost or expense and (iii) would not otherwise be disadvantageous to such Lender (as determined in its sole good faith discretion). Without limitation of the provisions of Section 12.14, each Borrower hereby agrees to pay all reasonable and documented, out-of-pocket costs and expenses incurred by any Lender in connection with any such designation or assignment.

(j) Subject to Section 2.2(c), if Agent determines (which determination shall be conclusive and binding absent manifest error) that Term SOFR cannot be determined pursuant to the definition thereof on or prior to the first day of any Interest Period, Agent will promptly so notify the Borrowers and each Lender. Upon notice thereof by Agent to Borrowers, any obligation of the Lenders to make SOFR Loans shall be suspended until Agent revokes such notice. Upon receipt of such notice, any outstanding affected SOFR Loans will be deemed to have been converted into Base Rate Loans at the end of the applicable Interest Period. Upon any such conversion, Borrower shall also pay any additional amounts required pursuant to this Agreement.

(k) If any Lender determines that any Law has made it unlawful, or that any Governmental Authority has asserted that it is unlawful, for any Lender or its applicable lending office to make, maintain or fund SOFR Loans, or to determine or charge interest rates based upon Term SOFR, then, upon notice thereof by such Lender to Borrowers (through Agent), any obligation of such Lender to make SOFR Loans shall be suspended, in each case until such Lender notifies Agent and Borrower that the circumstances giving rise to such determination no longer exist. Upon receipt of such notice, all SOFR Loans shall become Base Rate Loans. Upon any such conversion, Borrower shall also pay any additional amounts required pursuant to this Agreement.

(l) Each party's obligations under this Section 2.8 shall survive the resignation or replacement of Agent or any assignment of rights by, or the replacement of, a Lender, and the repayment, satisfaction or discharge of all Obligations hereunder.

(h) **Section 11.16 (Amendments and Waivers)**. Section 11.16(c) of the Existing Credit Agreement is hereby amended and restated as follows:

(c) Notwithstanding anything to the contrary in this Agreement or any other Financing Document, Agent may, without the consent of any Lender or Credit Party, enter into amendments or modifications to this Agreement or any of the other Financing Documents in order to implement any replacement of Term SOFR as contemplated in the definition thereof or any Conforming Changes or otherwise effectuate the terms of Section 2.2(c) in accordance with the terms of Section 2.2(c).

3. **Representations and Warranties; Reaffirmation of Security Interest**. Borrower hereby (a) confirms that all of the representations and warranties set forth in the Credit Agreement are true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct

in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) as of such earlier date and (b) covenants to perform its respective obligations under the Credit Agreement. Borrower confirms and agrees that all security interests and Liens granted to Agent continue in full force and effect, and all Collateral remains free and clear of any Liens, other than Permitted Liens. Nothing herein is intended to impair or limit the validity, priority or extent of Agent's security interests in and Liens on the Collateral. Borrower acknowledges and agrees that the Credit Agreement, the other Financing Documents and this Agreement constitute the legal, valid and binding obligation of Borrower, and are enforceable against Borrower in accordance with its terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws relating to the enforcement of creditors' rights generally and by general equitable principles.

4. **Conditions to Effectiveness**. This Agreement shall become effective as of the date on which each of the following conditions has been satisfied:

(a) Borrower shall have delivered to Agent this Agreement, duly executed by an authorized officer of Borrower;

(b) All representations and warranties of Borrower contained herein shall be true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) as of such earlier date (and such parties' delivery of their respective signatures hereto shall be deemed to be its certification thereof);

(c) Prior to and after giving effect to the agreements set forth herein, no Default or Event of Default shall exist under any of the Financing Documents;

(d) Borrower shall have paid to Agent and the Lenders all fees, charges, and other expenses which are then due and payable pursuant to the Credit Agreement; and

(e) Borrower shall have delivered such other documents, information, certificates, records, permits, and filings as the Agent may reasonably request.

5. **[Reserved]**.

6. **No Waiver or Novation**. The execution, delivery and effectiveness of this Agreement shall not, except as expressly provided in this Agreement, operate as a waiver of any right, power or remedy of Agent, nor constitute a waiver of any provision of the Credit Agreement, the Financing Documents or any other documents, instruments and agreements executed or delivered in connection with any of the foregoing. Nothing herein is intended or shall be construed as a waiver of any existing Defaults or Events of Default under the Credit Agreement or other Financing Documents or any of Agent's rights and remedies in respect of such Defaults or Events of Default. This Agreement (together with any other document executed in connection herewith) is not intended to be, nor shall it be construed as, a novation of the Credit Agreement.

7. **Affirmation**. Except as set forth herein, Borrower hereby acknowledges and agrees that the Credit Agreement and all other Financing Documents (and all covenants, terms, conditions and agreements therein) shall remain in full force and effect, and are hereby ratified and confirmed in all respects by Borrower. Borrower covenants and agrees to comply with all of the terms, covenants and conditions of the Credit Agreement and the Financing Documents, notwithstanding any prior course of conduct, waivers, releases or other actions or inactions on Agent's or any Lender's part which might otherwise constitute or be construed as a waiver of or amendment to such terms, covenants and conditions.

8. **Miscellaneous**.

(a) Reference to the Effect on the Credit Agreement. Upon the effectiveness of this Agreement, each reference in the Credit Agreement to "this Agreement," "hereunder," "hereof," "herein," or words of similar import shall mean and be a reference to the Credit Agreement, as modified by this Agreement. Except as specifically set forth above, the Credit Agreement, and all other Financing Documents (and all covenants, terms, conditions and agreements therein), shall remain in full force and effect, and are hereby ratified and confirmed in all respects by Borrower.

(b) THIS AGREEMENT AND THE RIGHTS, REMEDIES AND OBLIGATIONS OF THE PARTIES HERETO AND HERETO, AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS AGREEMENT, THE RELATIONSHIP OF THE PARTIES, AND/OR THE INTERPRETATION AND ENFORCEMENT OF THE RIGHTS AND DUTIES OF THE PARTIES AND ALL OTHER MATTERS RELATING HERETO, HERETO OR ARISING THEREFROM (WHETHER SOUNDING IN CONTRACT LAW, TORT LAW OR OTHERWISE), SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT REFERENCE TO ITS CONFLICT OF LAW PROVISIONS (OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW). NOTWITHSTANDING THE FOREGOING, AGENT AND LENDERS SHALL HAVE THE RIGHT TO BRING ANY ACTION OR PROCEEDING AGAINST ANY BORROWER OR ITS PROPERTY IN THE COURTS OF ANY OTHER JURISDICTION WHICH AGENT AND LENDERS (IN ACCORDANCE WITH THE PROVISIONS OF SECTION 12.1 OF THE CREDIT AGREEMENT) DEEM NECESSARY OR APPROPRIATE TO REALIZE ON THE COLLATERAL OR TO OTHERWISE ENFORCE AGENT'S AND LENDERS' RIGHTS AGAINST SUCH BORROWER OR ITS PROPERTY. EACH BORROWER EXPRESSLY SUBMITS AND CONSENTS IN ADVANCE TO THE JURISDICTION OF THE FEDERAL AND STATE COURTS LOCATED IN THE STATE OF NEW YORK IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, AND SUCH BORROWER HEREBY WAIVES ANY OBJECTION THAT IT MAY HAVE BASED UPON LACK OF PERSONAL JURISDICTION, IMPROPER VENUE, OR FORUM NON CONVENIENS AND HEREBY CONSENTS TO THE GRANTING OF SUCH LEGAL OR EQUITABLE RELIEF AS IS DEEMED APPROPRIATE BY SUCH COURT. EACH BORROWER HEREBY WAIVES PERSONAL SERVICE OF THE SUMMONS, COMPLAINTS, AND OTHER PROCESS ISSUED IN SUCH ACTION OR SUIT AND AGREES THAT SERVICE OF SUCH SUMMONS, COMPLAINTS, AND OTHER PROCESS MAY BE MADE BY REGISTERED OR CERTIFIED MAIL, RETURN RECEIPT REQUESTED, ADDRESSED TO SUCH BORROWER AT THE ADDRESS SET FORTH IN ARTICLE 11 OF THE CREDIT AGREEMENT AND SERVICE SO MADE SHALL BE COMPLETE TEN (10) DAYS AFTER THE SAME HAS BEEN POSTED. ***[Align with CAGR]***

(c) Incorporation of Credit Agreement Provisions. The provisions contained in Section 12.14 (Expenses; Indemnity) of the Credit Agreement are incorporated herein by reference to the same extent as if reproduced herein in their entirety.

(d) Headings. Section headings in this Agreement are included for convenience of reference only and shall not constitute a part of this Agreement for any other purpose.

(e) Counterparts. This Agreement may be signed in any number of counterparts, each of which shall be deemed an original and all of which when taken together shall constitute one and the same instrument. Delivery of an executed counterpart of this Agreement by facsimile or by electronic mail delivery of an electronic version (e.g., .pdf or .tif file) of an executed signature page shall be effective as delivery of an original executed counterpart hereof and shall bind the parties hereto.

(f) Entire Agreement. This Agreement constitutes the entire agreement and understanding among the parties hereto and supersedes any and all prior agreements and understandings, oral or written, relating to the subject matter hereof.

(g) Severability. In case any provision of or obligation under this Agreement shall be invalid, illegal or unenforceable in any applicable jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(h) Successors/Assigns. This Agreement shall bind, and the rights hereunder shall inure to, the respective successors and assigns of the parties hereto, subject to the provisions of the Credit Agreement and the other Financing Documents.

[SIGNATURES APPEAR ON FOLLOWING PAGES]

IN WITNESS WHEREOF, intending to be legally bound, and intending that this document constitute an agreement executed under seal, the undersigned have executed this Agreement as of the day and year first hereinabove set forth.

AGENT: **MIDCAP FINANCIAL TRUST,** a Delaware statutory trust By: Apollo Capital Management, L.P.,

its investment manager

By: Apollo Capital Management GP, LLC, its general partner

By: /s/ Maurice Amsellem Name: Maurice Amsellem

Title: Authorized Signatory [Signatures Continue

on Following Page]

LENDERS: MIDCAP FUNDING XIII TRUST

By: Apollo Capital Management, L.P., its investment manager

By: Apollo Capital Management GP, LLC, its general partner

By: /s/ Maurice Amsellem Name: Maurice Amsellem
Title: Authorized Signatory

ELM 2020-3 TRUST

By: MidCap Financial Services Capital Management, LLC, as Servicer

By: /s/ John O'Dea Name: John O'Dea
Title: Authorized Signatory

ELM 2020-4 TRUST

By: MidCap Financial Services Capital Management, LLC, as Servicer

By: /s/ John O'Dea Name: John O'Dea

Title: Authorized Signatory [Signatures

Continue on Following Page]

BORROWERS: CONFORMIS, INC.,
a Delaware corporation

By: /s/ Robert S. Howe Name: Robert S. Howe
Title: Chief Financial Officer and Treasurer

IMATX, INC.,
a California corporation

By: /s/ Robert S. Howe Name: Robert S. Howe

Title: Secretary

[End of Signature Pages]

Exhibit 21.1

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

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 1, 2023, 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, 2022. We consent to the incorporation by reference of said report in the Registration Statements of Conformis, Inc. on Forms S-8 (File No. 333-260883, File No. 333-256833, File No. 333-253879, 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. 333-237351).

/s/ GRANT THORNTON LLP

Boston, Massachusetts
March 1, 2023

Exhibit 31.1

CERTIFICATIONS

I, Mark A. Augusti, certify that:

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

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

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

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

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

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: 3/1/2023

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

Exhibit 31.2

CERTIFICATIONS

I, Robert Howe, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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: 3/1/2023

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

Exhibit 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Conformis, Inc. (the "Company") for the period ended December 31, 2022 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: 3/1/2023

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

Exhibit 32.2

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Conformis, Inc. (the "Company") for the period ended December 31, 2022 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: 3/1/2023

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