ConforMIS Inc
Form 10-K
March 24, 2016

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

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

OR

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

For the transition period from to

Commission file number: 001-37474

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

Delaware (State or other jurisdiction of incorporation or organization)	56-2463152 (I.R.S. Employer Identification Number)
28 Crosby Drive Bedford, MA (Address of principal executive offices)	01730 (Zip Code)

(781) 345-9001
(Registrant's telephone number, including area code)

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

Title of Class	Name of Exchange on Which Registered
Common Stock, $0.00001 par value	NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act:
None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	þ (Do not check if a smaller reporting company)	Smaller reporting company	¨

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

As of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, there was no established public market for the registrant's common stock, and therefore, the registrant cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date. The registrant's common stock began trading on the NASDAQ Global Market on July 1, 2015.

As of February 29, 2016, the registrant had 41,569,337 shares of Common Stock, $0.00001 par value per share, outstanding.

Portions of the registrant's definitive proxy statement for its 2016 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2015, are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K.

ConforMIS, Inc.

INDEX

PART I

Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

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

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

- our estimates regarding the potential market opportunity and timing of estimated commercialization for our current and future products, including our iTotal CR, our iTotal PS and, if we receive required marketing clearances or approvals, our iTotal Hip;
- our expectations regarding our sales, expenses, gross margins and other results of operations;
- our strategies for growth and sources of new sales;
- maintaining and expanding our customer base and our relationships with our independent sales representatives and distributors;
- our current and future products and plans to promote them;
- anticipated trends and challenges in our business and in the markets in which we operate;
- the implementation of our business model, strategic plans for our business, products, product candidates and technology;
- the future availability of raw materials used to manufacture, and finished components for, our products from third-party suppliers, including single source suppliers;
- product liability claims;
- patent infringement claims;
- the impact of our voluntary recall initiated in August 2015 on our business operations, financial results and customer relations;
- our ability to retain and hire necessary employees and to staff our operations appropriately;
- our ability to compete in our industry and with innovations by our competitors;
- potential reductions in reimbursement levels by third-party payors and cost containment efforts of accountable care organizations;
- our ability to protect proprietary technology and other intellectual property and potential claims against us for infringement of the intellectual property rights of third parties;
- potential challenges relating to changes in and compliance with governmental laws and regulations affecting our U.S. and international businesses, including regulations of the U.S. Food and Drug Administration and foreign government regulators, such as more stringent requirements for regulatory clearance of our products;
- the impact of federal legislation to reform the United States healthcare system and the reimposition of the 2.3 percent medical device excise tax if and when the current moratorium is lifted;
- the anticipated adequacy of our capital resources to meet the needs of our business; and

- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into. You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K and our other filings with the SEC completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

ITEM 1. BUSINESS

Overview

We are a medical technology company that uses our proprietary iFit Image-to-Implant technology platform to develop, manufacture and sell joint replacement implants that are individually sized and shaped, which we refer to as customized, to fit each patient's unique anatomy. The worldwide market for joint replacement products is approximately $15 billion annually and growing, and we believe our iFit technology platform is applicable to all major joints in this market. We believe we are the only company offering a broad line of customized knee implants designed to restore the natural shape of a patient's knee. We have sold a total of more than 40,000 knee implants in the United States and Europe. In clinical studies, iTotal CR, our cruciate-retaining total knee replacement implant and best-selling product, demonstrated superior clinical outcomes, including better function and greater patient satisfaction compared to traditional, off-the-shelf implants. In February 2015, we initiated the limited launch of iTotal PS, our posterior-stabilized total knee replacement implant which addresses the largest segment of the knee replacement market, and we initiated the broad commercial launch of the iTotal PS in March 2016.

Our iFit technology platform comprises three key elements:

- iFit Design, our proprietary algorithms and computer software that we use to design customized implants and associated single-use, patient-specific instrumentation, which we refer to as iJigs, based on a computed tomography, or CT, scan of the patient and to prepare a surgical plan customized for the patient that we call iView.
- iFit Printing, a three-dimensional, or 3D, printing technology that we use to manufacture iJigs and are in the process of extending to manufacture certain components of our customized knee replacement implants.
- iFit Just-in-Time Delivery, our just-in-time manufacturing and delivery capabilities.

We believe our iFit technology platform enables a scalable business model that greatly lowers our inventory requirements, reduces the amount of working capital required to support our operations and allows us to launch new products and product improvements more rapidly, as compared to manufacturers of traditional implants.

Manufacturers of traditional knee replacement implants offer products with a limited range of sizes and geometries, which we refer to as off-the-shelf implants. Off-the-shelf implants are not designed to restore a particular patient's unique anatomy. Our summary of one study indicates that approximately one in five patients who receives an off-the-shelf total knee replacement is not satisfied with the results. See "—Industry background—Knee implants" for a description of our summary of this study.

Based on clinical data developed independently by orthopedic surgeons comparing our iTotal CR to off-the-shelf total knee replacement implants, as well as our own research and the common approach we employ in the design and manufacture of our products, we believe that our customized knee replacement implants offer significant benefits to the patient, the surgeon and the hospital that are not afforded by off-the-shelf implants.

- For the patient. We believe that our individualized approach offers better clinical outcomes when compared to off-the-shelf implants based on the following measures:

Better fit. We design our customized knee implants to restore the patient's own native anatomy. As a result, we believe that our implants fit better.

Faster recovery. We believe an individual fit requires less bone and soft tissue removal by the surgeon, thereby shortening recovery times.

- Better function. We design our customized knee implants to follow the particular shape and contour of the patient's knee. As a result, we believe our implants offer an increased potential for a knee that moves more naturally and is more stable.

Greater patient satisfaction. We believe our implants offer patients greater overall satisfaction with the results of their knee replacement.

- For the surgeon. We believe that the combination of the use of our iJigs with our customized knee replacement implants enables a more accurate, reproducible and simplified surgical procedure by reducing the number of required steps and increasing the precision of the placement of the implant. Our summary of a retrospective study of 200 knee replacement surgeries published in 2014 in the peer-reviewed Journal of Arthroplasty, or the 2014 JOA Study, indicates that our iTotal CR implant was 1.8 times more likely to be in

the desired alignment range after surgery than an off-the-shelf implant. At the time this study was conducted, one of the authors of this study was a paid consultant to us.

- For the hospital. We believe that our customized knee replacement implants and iFit technology platform provide a better economic outcome for hospitals by:
  - improving patient recovery times, reducing blood loss and reducing adverse event rates at discharge;
  - reducing the costs associated with managing and sterilizing large numbers of reusable instruments; and
  - improving turnaround times with the potential for more procedures to be completed within the same amount of time and for the hospital to generate additional revenue.

As of February 29, 2016, we own or exclusively in-license a total of approximately 500 issued patents and pending patent applications that cover customized implants and patient-specific instrumentation, or PSI, for all major joints and other elements of our iFit technology platform. Our intellectual property portfolio includes 131 issued United States patents, 64 patents issued in countries outside the United States, and 313 patent applications worldwide. We believe that our patent portfolio provides a significant barrier to entry. On February 29, 2016, we filed a lawsuit against Smith & Nephew, Inc., or Smith & Nephew, in the United States District Court for the District of Massachusetts Eastern Division. The lawsuit alleges that Smith & Nephew's Visionaire® patient-specific instrumentation, as well as the implants systems used in conjunction with the Visionaire instrumentation, infringe eight of our patents and requests monetary damages for willful infringement and a permanent injunction.

Our knee replacement products have been cleared by the U. S. Food and Drig Administration, or FDA, under the premarket notification process of Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, and have received certification to CE Mark. We market our products to orthopedic surgeons, hospitals, hospital networks, ambulatory surgery centers and other medical facilities, and patients. We use direct sales representatives, independent sales representatives and distributors to market and sell our products in the United States, Germany, the United Kingdom and other markets.

We introduced our iUni and iDuo partial knee replacement products in 2007 and our iTotal CR in 2011. For the year ended December 31, 2015, we generated revenue of $63 million from product sales, representing a 30% increase over the prior year.

Industry background

Market opportunity

Joint replacement for treatment of osteoarthritis

Osteoarthritis is the principal condition that leads to joint replacement surgery. Osteoarthritis is a degenerative joint disease characterized by the breakdown of the cartilage that protects and cushions key joints in the body, including the knees, hips and shoulders. This causes the bones in the affected joint to rub against each other, which can result in significant and chronic joint pain, stiffness, swelling, numbness, loss of flexibility and loss of motor function. The pain of osteoarthritis, even during the early stages of the disease, can be overwhelming for patients and can have significant physical, psychological, quality of life and financial implications.

An estimated 27 million people in the United States and 630 million people worldwide suffer from osteoarthritis. Compelling demographic trends, such as the growing population of aging yet active individuals and rising rates of obesity, are expected to be key drivers in the continued growth of osteoarthritis occurrence. The National Institutes of Health, or NIH, projects that by 2030, approximately 70 million people in the United States will be 65 years or older and will be at high risk of developing osteoarthritis. Osteoarthritis is more common in adults over the age of 50, but the condition and precursors of the condition can be observed much earlier.

For moderate to advanced cases of osteoarthritis, a surgical procedure may be required to replace the damaged joint. During this joint replacement, or arthroplasty, procedure, a surgeon removes the damaged bone in the affected joint and inserts an implant as a replacement. The joint implant may replace all of the principal components of the joint, in which case the procedure is referred to as a total joint replacement, or may replace only a portion of the joint, in which case the procedure is referred to as a partial joint replacement. According to data from the American Academy of Orthopaedic Surgeons, or AAOS, most patients who undergo primary total knee arthroplasty, or TKA, and primary total hip arthroplasty, or THA, are aged 50 to 80 years old. However, our summary of presentations made at the 2014 annual meeting of the AAOS indicates that increased use of these procedures in

4

patients between 45 and 64 years old has fueled recent growth in the TKA and THA markets. Based on these trends, we expect patient demand for total joint replacements will continue to increase.

Joint replacement market

According to the Orthopaedic Industry Annual Report published in March 2015 by Orthoworld Inc., or the 2014 Orthoworld Report, worldwide sales of joint replacement products, including replacements for knees, hips, shoulders, elbows, wrists, ankles and digits outside of trauma, exceeded $15.4 billion in 2014 and are expected to grow to approximately $18 billion by the end of 2020. The 2014 Orthoworld Report estimated that worldwide sales of knee replacement products totaled approximately $7.5 billion in 2014. According to the Orthopaedic Industry Annual Report published in May 2014 by Orthoworld Inc., or the 2013 Orthoworld Report, 2013 estimated sales of knee replacement products in the United States represented approximately 56% of total estimated worldwide sales of such products.

According to the industry report U.S. Market for Large Bone and Joint Orthopedic Devices published in February 2014 by iData Research, or the iData Report, primary total knee replacement implants and partial knee replacement implants accounted for approximately 83% of the 2013 knee replacement market by revenue in the United States. The remaining 17% of the knee replacement market is for follow up procedures known as revision surgeries and patient-specific instruments. According to the iData Report, in 2013, of the primary total knee replacement market in the United States, posterior-stabilized procedures represented approximately 72% by revenue and cruciate-retaining procedures represented approximately 28% by revenue. The decision to perform a posterior-stabilized or cruciate-retaining total knee replacement is usually a matter of a surgeon's preferred surgical technique.

In 2014, according to the 2014 Orthoworld Report, worldwide sales of hip replacement products totaled approximately $6.3 billion. According to the 2013 Orthoworld Report, 2013 estimated sales of hip replacement products in the United States represented approximately 54% of total estimated worldwide sales of such products. According to the iData Report, primary total hip replacement implants accounted for approximately 69% by revenue of the 2013 hip replacement market in the United States.

The market for joint replacements extends beyond knee and hip replacements. For example, the treatment of osteoarthritis in the extremities, including the shoulder, elbow, wrist and digit, may involve the replacement of the affected joint. According to the 2014 Orthoworld Report, the worldwide extremities joint replacement market was estimated at $1.6 billion in 2014.

Knee implants

Knee replacement implants typically have four principal components:

- a metal femoral component that is placed over the end of the femur, which is the bone extending from the hip to the knee;
- a metal tibial component that is placed over the end of the tibia, which is the bone extending from the knee to the ankle;
- a plastic spacer typically made of polyethylene that is attached to the tibial component and is the surface across which the femoral component glides; and
- a plastic button typically made of polyethylene to resurface the knee cap, or patella.

The tibial and femoral components are attached to the patient's bone using acrylic cement. The surfaces where the metal components meet are referred to as articular surfaces.

Clinical shortcomings of off-the-shelf knee implants

Knees vary in size and shape; no two knees are the same. In a traditional knee replacement procedure, the surgeon must choose an off-the-shelf implant with a size and shape that the surgeon thinks will work best for the patient. However, off-the-shelf implants are not customized to fit an individual patient's knee, and during a knee replacement procedure, the surgeon has to fit the patient's soft tissue, bones and cartilage to the fixed dimensions of the implant through an iterative process of sizing and positioning. This typically entails removing bone and shaping the residual bone to the implant. Surgeons often have to make compromises on implant fit, rotation and alignment because the surgeons are limited by the size and shape of the implant. These compromises can cause residual pain and functional limitations after surgery, which we believe contribute to patient dissatisfaction. We reviewed a study of 1,703 patients published in 2009 in the peer-reviewed journal Clinical Orthopaedics and

5

Related Research where patient satisfaction was determined by combining patients who answered very dissatisfied, dissatisfied or neutral into one group and patients who answered satisfied or very satisfied into a second group. Our summary of the study indicates that approximately one in five patients who receive an off-the-shelf implant is not satisfied with his or her total knee replacement.

We believe that the typical compromises surgeons must make with off-the-shelf implants can affect patient outcomes in the following important ways:

- Improper implant fit. The femoral or tibial component of an off-the-shelf implant frequently protrudes beyond the edge of the bone, which is referred to as overhang. Overhang of three millimeters or greater is associated with an almost two fold increased risk of pain at two years after total knee replacement. Our summary of a study of 437 total knee replacements performed by a single surgeon with off-the-shelf implants published in 2010 in the peer-reviewed Journal of Bone and Joint Surgery indicates that 68% of women and 40% of men had femoral overhang of three millimeters or more. An off-the-shelf implant also may not fully cover the femur or the tibia, referred to as undersizing. Femoral and tibial undersizing may be associated with increased blood loss during surgery and an increased risk of osteolysis, or resorption and loss of bone, which may lead to costly transfusions and tibial implant loosening and failure.

The graphic below depicts femoral overhang, femoral undersizing, tibial overhang and tibial undersizing with an off-the-shelf knee implant:

- Component malrotation. The placement of the femoral or tibial component of an off-the-shelf implant frequently is not aligned, or is malrotated, with the proper rotational axis of the patient's knee. Our summary of a 2010 study published in the peer-reviewed Journal of Bone and Joint Surgery British indicates that 56% of painful total knee replacements were found to have significant rotational errors of the femoral and/or tibial components. In addition, our summary of a study of 28 total knee replacements with off-the-shelf implants published in 2001 in Clinical Orthopaedics and Related Research indicates that patients with improper component rotation were found to be five times more likely to experience knee pain than a control group of patients.

In order to achieve proper tibial rotation, there are often tradeoffs among proper sizing, coverage and placement with off-the-shelf implants. The graphic below depicts proper rotation and malrotation of the tibial component:

- Unnatural movement and feeling. The femoral component of an off-the-shelf implant has a fixed geometry that typically does not match the patient's natural curvatures, or "J" curves, of the surfaces of the condyles, which are the rounded lobes at the end of the femur. The femoral component of an off-the-shelf implant also does not match the inside, referred to as medial, or outside, referred to as lateral, joint lines. As a result, the implant may force the patient's knee into an unnatural motion that interferes with the normal functioning of the patient's ligaments. This frequently results in abnormal forward sliding of the femur during knee bend and up-and-down rocking, or lift off, of the condyles. Our summary of a study of 253 patients at least one year after total knee replacement with an off-the-shelf implant published in 2006 in Clinical Orthopaedics and Related Research indicates that dissatisfied patients reported that their knee did not feel normal at more than twice the rate of satisfied patients. In addition, our summary of an abstract presented at the 2014 International Congress for Joint Reconstruction Pan-Pacific Orthopedic Congress, or 2014 ICJR Pan-Pacific Congress, indicates that five of nine patients with off-the-shelf knee replacements implanted by the same surgeon experienced abnormal lift-off of their femoral condyles during a deep knee bend. We provided financial support for this study. At the time this study was conducted, one of the authors of this study also was a paid consultant to us.

The graphic below depicts abnormal femoral lift-off, one of the potential unnatural movements, in a knee replacement with an off-the-shelf implant.

Other challenges associated with off-the-shelf implants

In addition to the residual pain and functional limitations suffered by patients, we believe procedures using off-the-shelf knee implants present several intra-operative and economic challenges for surgeons and hospitals, including:

- For the surgeon. The surgical procedure is complex. Pre-operatively, the surgeon typically compares a two dimensional outline of the implant with the patient's x-ray images. This process provides only a rough estimate of the fit of the implant to the patient. Intra-operatively, the surgeon must perform repetitive and time-consuming cutting of tissue and fitting of trial implants. We believe that in many cases, the surgical procedure with an off-the-shelf knee implant involves more than 10 major steps and more than 100 sub-steps.

- For the hospital. We estimate that a total knee replacement procedure using an off-the-shelf implant requires approximately five to 10 costly double-tiered, sterilized instrument trays. Hospitals often store these trays from multiple manufacturers, occupying valuable space. Generally, the implant manufacturer provides these instruments to the hospital free of charge. However, the hospital must pay the cost of cleaning, sterilizing and storing the instruments between each surgical procedure. In addition, if instruments are not properly prepared, they are a potential source of costly infections. Many insurers and third-party payors, including Medicare, require the hospital to bear the costs of infections occurring within 90 days following a surgical procedure.

Recent efforts to improve traditional knee replacement surgery

In an effort to overcome some of the shortcomings associated with off-the-shelf implants, manufacturers have focused on improving traditional knee replacement procedures. We believe, however, that these efforts do not fully address the needs of patients, surgeons and hospitals:

- Patient-specific instrumentation, or PSI. Many manufacturers offer patient-specific instrumentation for use with their off-the-shelf implants. While this approach has the potential to reduce the number of trays and the quantity of instruments hospitals must manage, the patient still receives an off-the-shelf implant with the limitations described above.

- Robotic assistance. Some manufacturers offer robotic systems for use in planning and executing some types of knee replacement surgeries. These robotic systems are expensive to purchase and maintain. In addition, the patient still receives an off-the-shelf implant with the limitations described above.

- Increased range of sizes. Some manufacturers offer a greater range of sizes for their off-the-shelf implants, including gender-specific implants. Generally, however, these implants are limited by a fixed shape and size that do not conform to the unique geometry of each patient. As a result, these implants also are subject to the limitations described above.

The ConforMIS Solution: One Patient, One Implant

No two joints are the same; accordingly, we believe no two implants should be the same. We believe our customized joint replacement products and proprietary technology create an opportunity to disrupt the large, existing market for off-the-shelf orthopedic implants. Our summary of a survey of 356 orthopedic surgeons conducted by iData Research during the 2014 annual meeting of the American Academy of Orthopaedic Surgeons indicates that approximately 47% of respondents claimed to see a benefit to using custom implants.

We use our proprietary iFit Image-to-Implant technology platform to design and manufacture customized knee implants that are precisely sized and shaped to fit the unique three-dimensional curvatures of each patient's knee, as well as associated customized, single-use patient-specific instrumentation, which we refer to as iJigs. We believe our proprietary iFit technology platform is applicable to all major joints.

iFit Image-to-Implant technology platform

Our iFit technology platform comprises three key elements:

- iFit Design, our proprietary algorithms and computer software that we use to design customized implants and associated iJigs based on a CT scan of the patient and to prepare a surgical plan customized for the patient that we call iView.

- iFit Printing, a 3D printing technology that we use to manufacture iJigs and are in the process of extending to manufacture certain components of our customized knee replacement implants.

- iFit Just-in-Time Delivery, our just-in-time manufacturing and delivery capabilities. We manufacture the customized replacement joint and iJigs to order and do not maintain significant inventory of finished products. We deliver the customized knee replacement implant and iJigs to the hospital in advance of the scheduled arthroplasty procedure.

We believe our iFit technology platform enables a scalable business model that greatly lowers our inventory requirements, reduces the amount of working capital required to support our operations and allows us to launch new products and product improvements more rapidly, as compared to manufacturers of off-the-shelf implants.

Our customized implant procedure

The principal steps involved in the application of our iFit technology platform to the delivery of a customized knee implant to the hospital and surgical plan to the surgeon include:

CT scan

The surgeon orders a standard diagnostic CT scan of the patient's knee, along with a few CT images of the hip and ankle. The CT scan is then sent to ConforMIS.

Recreating the knee using three-dimensional modeling

We use our proprietary algorithms and computer software to map the articular surfaces of the knee joint, define the areas of disease and convert the imaging data into a three-dimensional model of the knee. Our software is designed to correct for deformities caused by osteoarthritis and to digitally recreate the biomechanical axes of the patient's knee, which is important in determining proper rotation and alignment of the implant.

Personalizing the implant

Our engineers use computer-aided design, or CAD, software to design the customized implant and iJigs that will precisely match the three-dimensional model of the patient's knee. We are able to model the implant contact surfaces and maximize contact area for each patient with the goal of reducing polyethylene wear, a common reason for implant failure.

Development of patient-specific surgical plan

For each patient, we generate and provide the surgeon with iView, which allows the surgeon to visualize all preoperative planning information, including surgical steps, measurements and orientations. We make iView available to the surgeon electronically in advance of the procedure and include iView in a single package with our customized implant and iJigs.

Just-in-time delivery to hospital

We deliver the patient's customized knee implant and iJigs to the hospital in advance of the surgery. We are able to deliver our products within six weeks in the United States and seven weeks internationally of the date of our receipt of an order, which includes a CT scan and an implant request form from the surgeon.

Key benefits of our customized products

We use our iFit technology platform to develop customized joint replacement systems and single-use surgical instruments. Based on clinical data developed independently by orthopedic surgeons comparing our iTotal CR to off-the-shelf total knee replacement implants, as well as our own research and the common approach we employ in the design and manufacture of all of our products, we believe that our customized knee replacement implants offer significant benefits to the patient, the surgeon and the hospital that are not afforded by off-the-shelf implants.

- For the patient. We believe that our individualized approach offers better clinical outcomes when compared to off-the-shelf implants based on the following measures:

Better fit. Using our proprietary algorithms and computer software, we design our customized knee implants to restore the patient's own native anatomy, avoid femoral and tibial overhang and undersizing and provide proper tibial component rotation. As a result, we believe that our implants fit better, which is important to minimize pain and maintain the integrity of the implant.

Faster recovery. We believe an individual fit requires less bone and soft tissue removal by the surgeon, resulting in less bleeding and swelling within the knee and shortened recovery times. Our summary of a study of 132 total knee replacements presented at the 2013 Annual Meeting of the British Association for Surgery of the Knee, or the 2013 BASK Study, indicates that the use of our iTotal CR resulted in a statistically significant reduction in bone resections ($p<0.001$), thereby preserving more of the patient's bone, and required statistically significantly fewer soft tissue cuts ($p=0.046$) than an off-the-shelf implant. We determine statistical significance based on a widely used, conventional statistical method that establishes the p-value of observed results. Typically, a p-value of 0.05 or less represents statistical significance, meaning that there is less than a one-in-20 likelihood that the observed results occurred by chance. The investigator who conducted this study was a paid consultant to us and a member of our scientific advisory board at the time this study was conducted.

Better function. We design our customized implants to match the patient's natural "J" curves, corrected for deformities caused by osteoarthritis, preserve the patient's medial and lateral joint lines, and minimize up-and-down rocking and lift-off of the patient's condyles during normal knee movement. As a result, we believe that our implants have the potential to offer a more stable, natural feeling knee with normal kinematic pattern and function. Our summary of an abstract presenting ConforMIS-sponsored research at the 2014 ICJR Pan-Pacific Congress indicates that 10 of 11 patients studied with an iTotal CR as compared to only five of nine patients studied with off-the-shelf knee replacements showed a normal motion pattern for the lateral condyle during a deep knee bend. All procedures were performed by the same surgeon. This differential between the two groups was observed despite the apparent success of the implant procedure in all 20 patients based on a commonly used scoring system. We provided financial support for this study. One of the authors of this study also were paid consultants to us, and one of them was a member of our scientific advisory board at the time this study was conducted.

Greater patient satisfaction. We believe our customized implants offer patients greater overall satisfaction with the results of their knee replacement. Our summary of a retrospective study of 70 patients who had undergone total knee replacement presented at the 2015 International Congress for Joint Reconstruction World Arthroplasty Congress, or 2015 ICJR World Arthroplasty Congress, indicates that the self-reported patient satisfaction score was statistically significantly higher in patients who had received our iTotal CR ($p=0.04$) than in a control group of patients who had received an off-the-shelf knee implant.

Earlier intervention. We believe that patients who undergo knee replacement with one of our products typically retain more of their bone during the surgical procedure, as compared to patients who undergo knee replacement using an off-the-shelf implant. The more bone that is preserved, the more likely the patient will have sufficie