ConforMIS Inc
Form 10-K
March 09, 2018

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, 2017

OR

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

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

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

(781) 345-9001
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

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

Securities registered pursuant to Section 12(g) of the Act:
None.
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No þ

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No ¨

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

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

Large accelerated filer	o	Accelerated filer	x
Non-accelerated filer	o (Do not check if a smaller reporting company)	Smaller reporting company	o
		Emerging growth company	x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

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

The aggregate market value of Common Stock held by non-affiliates of the registrant computed by reference to the price of the registrant's Common Stock as of the last business day of the registrant's most recently completed second fiscal quarter (based on the last reported sale price on The Nasdaq Global Select Market as of such date) was $94,870,205. As of February 28, 2018 there were 60,861,852 shares of the registrant's Common Stock, $.00001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2017. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

ConforMIS, Inc.

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PART I

Forward-Looking Statements

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

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

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

- our estimates regarding the potential market opportunity and timing of estimated commercialization for our current and future products, including our iUni, iDuo, iTotal CR, iTotal PS and ConforMIS Hip System, which we previously referred to as our iTotal Hip system;
- our expectations regarding our sales, expenses, gross margin and other results of operations;
- our strategies for growth and sources of new sales;
- maintaining and expanding our customer base and our relationships with our independent sales representatives and distributors;
- our current and future products and plans to promote them;
- anticipated trends and challenges in our business and in the markets in which we operate;
- the implementation of our business model, strategic plans for our business, products, product candidates and technology;
- the anticipated timing of our product launches;
- the future availability of raw materials used to manufacture, and finished components for, our products from third-party suppliers, including single source suppliers;
- product liability claims;
- patent infringement claims;
- our ability to retain and hire necessary employees and to staff our operations appropriately;
- our ability to compete in our industry and with innovations by our competitors;
- potential reductions in reimbursement levels by third-party payors and cost containment efforts of accountable care organizations;
- our ability to protect proprietary technology and other intellectual property and potential claims against us for infringement of the intellectual property rights of third parties;
- potential challenges relating to changes in and compliance with governmental laws and regulations affecting our U.S. and international businesses, including regulations of the U.S. Food and Drug Administration and foreign government regulators, such as more stringent requirements for regulatory clearance of our products;
- the anticipated adequacy of our capital resources to meet the needs of our business or our ability to raise any additional capital; 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 $17.5 billion annually and growing, and we believe our iFit technology platform is applicable to all major joints in this market. We offer a broad line of customized knee implants designed to restore the natural shape of a patient's knee. We have sold a total of more than 50,000 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 off-the-shelf implants. In March 2016, we initiated the broad commercial launch of the iTotal PS, our posterior-stabilized total knee replacement implant which addresses the largest segment of the knee replacement market.

Our iFit technology platform comprises three key elements:

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

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

Manufacturers of traditional knee replacement implants offer products with a limited range of sizes and geometries, which we refer to as off-the-shelf implants. Off-the-shelf implants are not designed to restore a particular patient's unique anatomy.

Based on clinical data developed independently by orthopedic surgeons comparing our iTotal CR to off-the-shelf total knee replacement implants, as well as our own research and the common approach we employ in the design and manufacture of our products, we believe that our customized knee replacement implants offer significant benefits to patients, surgeons and hospitals 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. A study of 63 knee replacement surgeries, published in 2017 in the peer-reviewed Journal of Knee Surgery, indicates that 84% of patients achieved perfect neutral coronal mechanical alignment after surgery, and that 100% of patients were within the desired alignment range after surgery. Similarly, a prior retrospective study of 200 knee replacement surgeries published in 2014 in the peer-reviewed Journal of Arthroplasty, or the 2014 JOA Study, indicated that our iTotal CR implant was 1.8 times more likely to be in the desired alignment range after surgery than an off-the-shelf implant. At the time the 2014 JOA Study was conducted, one of the authors of this study was a paid consultant to us.

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- 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;
- reducing the costs associated with managing and sterilizing large numbers of reusable instruments;
- improving turnaround times with the potential for more procedures to be completed within the same amount of time and for the hospital to generate additional revenue.

As of February 28, 2018, we own or exclusively in-license a total of approximately 420 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 148 issued United States patents, 67 patents issued in countries outside the United States, and 205 patent applications worldwide. See Note J - "Legal Proceedings" in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K for information regarding our patent litigation.

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

Industry background

Market opportunity

Joint replacement for treatment of osteoarthritis

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

An estimated 27 million people in the United States and 630 million people worldwide suffer from osteoarthritis. Compelling demographic trends, such as the growing population of aging yet active individuals and rising rates of obesity, are expected to be key drivers in the continued growth of osteoarthritis occurrence. The National Institutes of Health, or NIH, projects that by 2030, approximately 70 million people in the United States will be 65 years or older and will be at high risk of developing osteoarthritis. Osteoarthritis is more common in adults over the age of 50, but the condition and precursors of the condition can be observed much earlier. For moderate to advanced cases of osteoarthritis, a surgical procedure may be required to replace the damaged joint. During this joint replacement, or arthroplasty, procedure, a surgeon removes the damaged bone in the affected joint and inserts an implant as a replacement. The joint implant may replace all of the principal components of the joint, in which case the procedure is referred to as a total joint replacement, or may replace only a portion of the joint, in which case the procedure is referred to as a partial joint replacement.

Joint replacement market

According to the Orthopaedic Industry Annual Report for the 2016 calendar year, which was published in May 2017 by Orthoworld Inc., or the 2016 Orthoworld Report, worldwide sales of joint replacement products, including replacements for knees, hips, shoulders, elbows, wrists, ankles and digits outside of trauma, exceeded $17.5 billion in 2016 and are expected to grow to approximately $21 billion by the end of 2021. The 2016 Orthoworld Report estimated that worldwide sales of knee replacement products totaled approximately $8.5 billion and the United States represented approximately 49% of total estimated worldwide sales of such products. In 2016, according to the 2016 Orthoworld Report, worldwide sales of hip replacement products totaled approximately $6.9 billion. According to the 2016 Orthoworld Report, 2016 estimated sales of hip replacement products in the United States represented approximately 40% of total estimated worldwide sales of such products. According to the 2013 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 2016 Orthoworld Report, the worldwide extremities joint replacement market was estimated at $1.9 billion in 2016.

The ConforMIS Solution: One Patient, One Implant

No two joints are the same; accordingly, we believe no two implants should be the same. We believe our customized joint replacement products and proprietary technology create an opportunity to disrupt the large, existing market for off-the-shelf orthopedic implants. We use our proprietary iFit Image-to-Implant technology platform to design and manufacture customized knee implants that are precisely sized and shaped to fit the unique three-dimensional curvatures of each patient's knee, as well as associated customized, single-use patient-specific instrumentation, which we refer to as iJigs. We believe our proprietary iFit technology platform is applicable to all major joints.

iFit Image-to-Implant technology platform

Our iFit technology platform comprises three key elements:

- iFit Design, our proprietary algorithms and computer software that we use to design customized implants and associated iJigs based on a CT scan of the patient and to prepare a surgical plan customized for the patient that we call iView.
- iFit Printing, a 3D printing technology that we use to manufacture iJigs and may extend to manufacture certain components of our customized 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

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 patients, surgeons and hospitals 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.

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.

Greater patient satisfaction. We believe that, as a result of our customized implants fitting and functioning better, patients have greater overall satisfaction with the results of their knee replacement.

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 sufficient bone available if a revision surgery is necessary. As a result, patients may undergo knee replacement surgery at an earlier age.

- For the surgeon. We believe that our iFit technology platform offers an improved surgical procedure and greater efficiencies for surgeons when compared to knee replacements with off-the-shelf implants based on the following measures:

Improved surgical procedure. We believe that the combination of the use of our iJigs with our customized knee implants enable a more accurate, reproducible and simplified surgical procedure by reducing the number of steps and increasing the precision of implant alignment. In our procedure, the surgeon makes a predetermined number of cuts that are specifically tailored to each patient and designed to result in a precise fit without the need for repetitive cutting of tissue and fitting of trial implants associated with an off-the-shelf knee replacement.

Bone preservation. We believe our knee implants result in the preservation of more bone for several reasons:

We use our iFit technology platform to design each of the bone cuts required to fit our customized implants so as to minimize bone resection and maximize bone preservation for the individual patient.

Our femoral component is fitted using six cuts of the femur as compared to the five cuts typically used with off-the-shelf implants. We reviewed an abstract presented at the 2012 Annual Meeting of the British Association for Surgery of the Knee, which studied stress and fatigue in a six-cut femoral implant model that was thinner than a five-cut model by an average of two millimeters. The six-cut implant model displayed substantially lower maximum stress than a five-cut model at a known high-stress location. At the time of the study, two of the authors of this study were our employees, and two of the authors of this study were paid consultants to us. Based in part on this data, we believe our six-cut implants can be thinner than off-the-shelf implants without sacrificing implant strength. We believe a thinner implant requires the surgeon to remove less bone during implantation.

Our summary of a peer reviewed study of 169 implants published in Reconstructive Review in 2016 indicates that our iTotal CR showed statistically significant less bone loss resection ($p \leq 0.05$) when compared to off-the-shelf implants. At the time of the study, two of the authors of this study were our employees, and one of the authors of this study was a paid consultant to us.

As a result, we believe our implants may appeal particularly to surgeons who treat young, active patients. The surgeons might otherwise recommend postponing surgery out of fear that the patient will not be eligible for a revision surgery if one becomes necessary.

Fewer post-operative issues. We believe our customized knee implants reduce the number of post-operative issues. Our review of a retrospective study of 248 patients who had undergone a total knee replacement, published in the peer-reviewed journal Arthroplasty Today in 2017, or the 2017 AT Study, indicates that patients who received an iTotal CR had significantly lower transfusion rates ($p=0.005$) and adverse event rates at discharge ($p=0.003$) and at 90 days post-discharge ($p=0.023$) than patients who received an off-the-shelf total knee replacement implant. We provided financial support for this study. At the time of this study, one of the authors of this study was a paid consultant to us.

Greater efficiency. Because of the simplified surgical procedure used with our products, we believe total operating room time is reduced when implanting an iTotal CR as compared to an off-the-shelf implant. 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.

- For the hospital. We believe that our customized implants and iFit technology platform provide a better economic outcome for hospitals through:

Improved implant and instrument management and reduced sterilization costs. As a result of our just-in-time delivery model, we ship our knee 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. In addition, we estimate that a total knee replacement procedure using an off-the-shelf implant requires approximately five to 10 double-tiered, instrument trays, which must be cleaned, sterilized and stored

between procedures at significant cost to the hospital. A knee replacement procedure using our iTotal CR product requires only one tray 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 an off-the-shelf implant, we believe our products meaningfully reduce a hospital'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 an off-the-shelf product. 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 replacements with our customized total knee implants can improve turnaround times with the potential for more procedures to be completed within the same amount of time and for hospitals to generate additional revenue.

- Shorter stays. We believe that our customized total knee replacements may shorten hospital stays. Our summary of the results of the 2017 AT Study indicates that a statistically significantly greater percentage of patients who underwent total knee replacement were discharged in fewer than three days following surgery (p=0.037) in the iTotal CR group (42%) than in the off-the-shelf group (30%). Our summary of a study presented at the ICJR Pan Pacific Orthopaedic Congress in 2016, of 62 patients with either our iTotal CR or an off-the-shelf implant in a “Fast Track” protocol, also indicates that a significantly higher (p≤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 and payors. For example, the 2017 AT Study compared adverse events rates and cost of care for total knee arthroplasty (TKA) patients treated with either customized individually made (CIM) implants or standard off-the-shelf (OTS) implants. In that study, the total average real hospital costs between the customized implant and OTS 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 $913.87 per patient for the customized implant group for bundle of care, including the preoperative computed tomography scan, TKA hospitalization, and discharge disposition. Follow-up care costs demonstrated a savings of $1,313 per patient.

- Fewer adverse events. Many insurers and third-party payors, including Medicare, require the hospital 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 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 may not be reimbursed for additional post-operative follow up care during this period.

Our strategy

Our objective is for our customized implants to become the standard of care for orthopedic joint replacement surgery. We believe that our iFit Image-to-Implant technology platform will enable us to offer a wide variety of customized joint replacement implants with superior performance that offer key clinical and economic benefits over off-the-shelf implants. Key elements of our strategy to achieve our objective are to:

- Expand our sales efforts to drive adoption of our products. We systematically analyze market opportunities by considering factors such as the number of orthopedic surgeons, procedure volumes, pricing and reimbursement. We often seek to penetrate these markets by establishing relationships with influential surgeons who perform a high-volume of joint replacement procedures. We work with these surgeons to educate other surgeons.

- Leverage the clinical and economic benefits of our products and technologies. We believe our customized knee implant products offer important clinical and economic benefits to patients, surgeons and hospitals. Potential benefits include better function, less bone resection, less blood loss, greater patient satisfaction, reduced length of stay and lower adverse event rates. These potential economic benefits for hospitals also include reduced procedure times and reduced instrument management, cleaning and sterilization costs. We believe that our iFit technology platform will allow us to offer products for other joints that also afford important clinical and economic benefits. We have designed and sponsored studies that support these clinical and economic data. We will continue to establish these potential benefits through the design and sponsoring of studies to increase our available clinical and economic data.

- Broaden our product portfolio by launching additional customized orthopedic implants. While our initial focus has been on the knee implant market, we believe our iFit technology platform is applicable to customized implants for all major joints in the body and multiple implant subcategories within each joint. In 2015, we initiated the limited launch of iTotal PS, our posterior-stabilized total knee replacement implant, to address the largest segment of the knee replacement market, and we initiated the broad commercial launch of iTotal PS in March 2016. In 2017, we received clearance from the FDA for the ConforMIS Hip System, our first customized hip replacement implant, which we plan to launch on a limited basis in the second half of 2018. Additionally, we are currently developing the next generation of our iUni partial knee replacement system, which we expect to launch on a limited basis in the first half of 2019, and we are developing the next generation of our iTotal CR and iTotal PS systems. We expect to launch the next generation of the iTotal CR in the second half of 2019, including the launch of instrumentation that will be used in our next generation iTotal PS system. We also may seek to apply our iFit technology platform to develop additional product opportunities in the knee and hip replacement markets and other orthopedic markets in the longer-term, including shoulder, other extremities, spine and ligament reconstruction.

- Expand our just-in-time manufacturing processes. We have built state of the art manufacturing processes, including proprietary software and 3D printing capabilities. We are continuing to invest in these processes, as we believe they provide us important competitive advantages, including:
  - expansion of gross margin through various initiatives, including the ongoing vertical integration of some of our manufacturing processes;
  - shorter product design and development time frames; and
  - continuous improvement of our products without making obsolete a large inventory of implants and instruments, in contrast to manufacturers of off-the-shelf implants;

- Enhance our patent portfolio and continue to exploit our patent position. As of February 28, 2018, we own or exclusively in-license a total of approximately 420 issued patents and pending patent applications that cover customized implants and PSI for all major joints and other elements of our iFit technology platform. See Note J - "Commitments and Contingencies" in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K for information regarding our patent litigation.

Our products

Knee replacement products

We offer a broad line of primary knee replacement implants, both partial and total, that we customize to fit the individual patient. Surgeons use our family of customized knee implants to treat mild to severe osteoarthritis of the knee. All of our knee replacement products have been cleared by the FDA under the premarket notification process of Section 510(k) of the FDCA and have received certification to CE Mark. We deliver our customized knee replacement implants and iJigs, together with iView, to the hospital in a single pre-sterilized package in advance of the scheduled arthroplasty procedure.

The following is an overview of each of our knee replacement implant products:

iTotal CR is the only cruciate-retaining, customized total knee replacement system on the market designed to restore the natural shape of a patient's knee. We introduced the iTotal CR in May 2011 and launched new generations in each of 2012, 2013 and 2015. The iTotal CR includes a femoral implant, a tibial tray, and dual medial and lateral polyethylene inserts, which serve as a cushion between the femoral and tibial components, all of which are individually made for the particular patient, together with a polyethylene patella designed to work with our customized components.

The iTotal PS is the only posterior cruciate ligament substituti