NUVASIVE INC
Form 10-K
February 09, 2017

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, 2016

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: 000-50744

NUVASIVE, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	33-0768598 (I.R.S. Employer Identification No.)
7475 Lusk Boulevard San Diego, California (Address of principal executive offices)	92121 (Zip Code)

(858) 909-1800

(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, par value $0.001 per share	The NASDAQ Stock Market LLC (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 of 1933, as amended. 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 Securities Exchange Act of 1934, as amended. 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 than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of 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.

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. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer (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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $3.0 billion as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2016), based upon the closing sale price for the registrant's common stock on that day as reported by the NASDAQ Global Select Market. Shares of common stock held by each officer and director on June 30, 2016 have

been excluded in that such persons may be deemed to be affiliates.

As of February 6, 2017, there were 50,599,338 shares of the registrant's common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Form 10-K incorporates information by reference to portions of the definitive Proxy Statement for the registrant's 2017 Annual Meeting of Stockholders, which will be filed with the U.S. Securities and Exchange Commission not later than 120 days after December 31, 2016.

NuVasive, Inc.

Annual Report on Form 10-K for the Fiscal Year ended December 31, 2016

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PART I

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements that involve risks, uncertainties, assumptions and other factors which, if they do not materialize or prove correct, could cause our results to differ from historical results or those expressed or implied by such forward-looking statements. In some cases, you can identify these forward-looking statements by words like "may", "will", "should", "could", "expect", "plan", "anticipate", "believes", "estimates", "predicts", "potential", "intends", or "continues" (or the negative of those words and other comparable words). Forward-looking statements include, but are not limited to, statements about:

- our intentions, beliefs and expectations regarding our expenses, sales, operations and future financial performance;
- our operating results;
- our plans for future products and enhancements of existing products;
- anticipated growth and trends in our business;
- the timing of and our ability to maintain and obtain regulatory clearances or approvals;
- our belief that our cash and cash equivalents and investments will be sufficient to satisfy our anticipated cash requirements;
- our expectations regarding our revenues, customers and distributors;
- our beliefs and expectations regarding our market penetration and expansion efforts;
- our expectations regarding the benefits and integration of recently-acquired businesses and our ability to make future acquisitions and successfully integrate any such future-acquired businesses;
- our anticipated trends and challenges in the markets in which we operate; and
- our expectations and beliefs regarding and the impact of investigations, claims and litigation.

These statements are not guarantees of future performance or events. Our actual results may differ materially from those discussed in this Annual Report and the documents incorporated by reference to this Annual Report. The potential risks and uncertainties that could cause actual results to differ materially include, but are not limited to, those set forth in Part I, Item 1(A) under the heading "Risk Factors", Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Annual Report and in any other documents incorporated by reference to this Annual Report. Readers are cautioned not to place undue reliance on such forward-looking statements. We assume no obligation to update any forward-looking statements to reflect new information, future events or circumstances or otherwise, except as required by law.

This Annual Report and the documents incorporated by reference into this Annual Report refer to trademarks, such as Absolute Responsiveness®, Acuity®, Affix®, Armada®, AttraX®, Back Pact®, Bendini®, Better Back Alliance®, Better Insight. Better Decisions. Better Medicine®, Brigade®, CerPass®, CoRoent®, Creative Spine Technology®, DBR®, Embody®, Embrace®, ExtenSure®, Formagraft®, Gradient Plus®, Halo®, iGA™, ILIF®, InStim®, LessRay®, Leverage®, MAGEC®, MAGEC-EOS™, MAS®, MaXcess®, NeoDisc™, Nerve Avoidance Leader™, NuvaMap™, NuvaLine™, NuvaMap™ O.R., NuVasive®, NVM5®, Osteocel®, Precept®, PRECICE®, PROPEL®, Radian®, Reline™, Speed of Innovation®, SpheRx®, The Better Way Back®, Traverse®, Triad®, VuePoint®, X-Core®, and XLIF®, which are protected under applicable intellectual property laws and are our property or the property of our subsidiaries. Solely for convenience, our trademarks and tradenames referred to in this Annual Report may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

Item 1.Business

Overview

We are a leading medical device company in the global spine surgery market, focused on developing minimally-disruptive surgical products and procedurally-integrated solutions for spine surgery. Currently, our

marketed product portfolio is focused on applications for spine fusion surgery, including biologics used to aid in the spinal fusion process. For the year ended December 31, 2016, we generated global revenues of $962.1 million, including sales in over 40 countries.

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Our principal product offering includes a minimally-disruptive surgical platform called Maximum Access Surgery, or MAS. The MAS platform combines three categories of solutions that collectively minimize soft tissue disruption during spine fusion surgery, provide maximum visualization and are designed to enable safe and reproducible outcomes for the surgeon and the patient. The platform includes our proprietary software-driven nerve detection and avoidance systems, NVM5, and Intraoperative Monitoring, or IOM, services and support; MaXcess, an integrated split-blade retractor system; and a wide variety of specialized implants and biologics. Many of our products, including the individual components of our MAS platform can also be used in open or traditional spine surgery. Our spine surgery product line offerings, which include products for the thoracolumbar and the cervical spine, are primarily used to enable surgeon access to the spine to perform restorative and fusion procedures in a minimally-disruptive fashion. In May 2015, we launched Integrated Global Alignment, or iGA, in which products and computer assisted technology under our MAS platform help achieve more precise spinal alignment. Our biologics products, which are used to aid in the spinal fusion process or bone healing process, include allograft (donated human tissue) and synthetic offerings.

We believe our MAS platform and its related offerings provide a unique and comprehensive solution for the safe and reproducible minimally-disruptive surgical treatment of spine disorders by enabling surgeons to access the spine in a manner that affords both direct visualization and detection and avoidance of critical nerves. The fundamental difference between our MAS platform, which is sometimes referred to in the industry as “minimally invasive surgery” or “MIS”, is the ability to customize safe and reproducible access to the spine while allowing surgeons to continue to use instruments that are familiar to them and effective during surgery. Accordingly, the MAS platform does not force surgeons to reinvent or learn new approaches that add complexity and undermine safety, ease of use and/or efficacy. We have dedicated and continue to dedicate significant resources toward training spine surgeons around the world; both those who are new to our MAS and other product platforms, as well as ongoing education for MAS-trained surgeons attending advanced courses. An important ongoing objective of ours has been to maintain a leading position in access and nerve avoidance, as well as to pioneer and remain the ongoing leader in minimally invasive spine surgery. Our MAS platform, with the unique advantages provided by our nerve monitoring systems, enables an innovative lateral procedure known as eXtreme Lateral Interbody Fusion, or XLIF, in which surgeons access the spine for a fusion procedure from the side of the patient’s body, rather than from the front or back. It has been demonstrated clinically that XLIF and other procedures facilitated by our MAS platform decrease trauma and blood loss, and lead to faster overall patient recovery times compared to open spine surgery.

We continue to focus significant research and development efforts to expand our MAS and other product platforms and advance the applications of our unique technology into procedurally-integrated surgical solutions that improve clinical and economic outcomes. During 2016, we acquired businesses and technologies to further expand our product and services offerings and drive growth in our business:

- In February 2016, we acquired Ellipse Technologies, Inc., or Ellipse Technologies, which developed and commercialized expandable growing rod implant systems that can be non-invasively lengthened following implantation with precise, incremental adjustments via an external remote controller using magnetic technology called MAGnetic External Control, or MAGEC. Following the acquisition, these product offerings are now sold by our NuVasive Specialized Orthopedics division, or NSO.
- In July 2016, we acquired BNN Holdings Corp., which through its subsidiaries and affiliates, owns and operates Biotronic NeuroNetwork, a patient-centric healthcare organization that provides intraoperative neurophysiological monitoring services to surgeons and healthcare facilities across the U.S. Following the acquisition, we combined the service offerings of Biotronic NeuroNetwork with our existing IOM business, Impulse Monitoring, Inc., under the newly created division NuVasive Clinical Services, or NCS.
- In September 2016, we acquired the LessRay software technology suite, which is designed to be integrated into current surgeon workflow and utilizes an algorithm to drive image registration and help surgeons and hospital staff manage radiation exposure using low-dose image quality enhancement. This technology is expected to become an

integral component of our IOM service and MAS platform.

We expect to continue to pursue business and technology acquisitions targets, strategic partnerships and out of the box thinking to identify opportunities to broaden participation along the spine care continuum. Top priorities include opportunities that complement our technology leadership position in spine, targeted geographic expansion, technology that makes procedures even safer, as well as opportunities for imaging and navigation.

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Our corporate headquarters is located in San Diego, California where we occupy approximately 154,000 square feet, including a six-suite state-of-the-art cadaver operating theatre designed to accommodate the training of spine surgeons. Our location in Amsterdam, the Netherlands, serves as our international headquarters. Our NSO division is based in Aliso Viejo, California, and our NCS division has corporate offices in Columbia, Maryland and Ann Arbor, Michigan. Our primary distribution and warehousing operations are located in our facility in Memphis, Tennessee. Our business is facilitated by rapid delivery of products and surgical instruments for surgeries involving our products. Because of its location and proximity to overnight third-party transporters, our Memphis facility enhances our ability to meet demanding delivery schedules and provide a greater level of customer service. Additionally, we have a manufacturing facility located in West Carrollton, Ohio that produces spinal implants. In furtherance of our initiative to increase the amount of products that we self-manufacture, in 2015 we added an approximately 180,000 square foot manufacturing facility in West Carrollton, Ohio. Throughout 2016, we have worked to build out and equip the new facility in order to expand our internal manufacturing efforts, and initial production is underway.

Our Strategy

We are a leading provider of innovative medical products that provide comprehensive solutions for the surgical treatment of spine disorders. We continue to pursue the following business strategies in order to improve our competitive position:

- Establish our MAS Platform as the Standard of Care. We believe our MAS platform has the potential to become the standard of care for spine surgery as hospitals, providers and spine surgeons continue to recognize its many benefits and adopt our products and procedures. We also believe our MAS platform has the potential to dramatically improve the clinical results of spine surgery. Because of this belief, we dedicate significant resources to researching clinical outcomes data as well as educating spine surgeons, hospitals, and other providers and their patients on the clinical and financial benefits of our products, and we intend to capitalize on the growing demand for minimally-disruptive surgical procedures.
- Continue to Develop and Introduce Procedurally-Integrated Solutions and New Innovative Products. One of our core competencies is our ability to rapidly develop and commercialize innovative spine surgery products and procedures to fulfill an unmet clinical need. In the past several years, we have introduced a continual flow of new products and product enhancements. We have additional products and procedural offerings currently under development that should expand our presence in fusion surgery. With our comprehensive portfolio of product and service offerings, we believe that we can offer our customers a comprehensive procedural solution for spine surgery that distinguishes us from traditional spine implant companies. We intend to continue to build upon our procedural solution with new and enhanced technology offerings, as well as product expansions. We believe through continued innovation and a focus on providing comprehensive procedural solutions for our customers, we will increase our market share while at the same time improving patient care. As part of this strategy, the Company must continue to protect and defend its intellectual property related to our innovative products.
- Expand the Reach of Our Exclusive Sales Force. We believe having a sales force dedicated to selling only our products is critical to achieving continued growth across our various product lines, driving greater market penetration and increasing our revenues. In the United States, we have an exclusive sales force consisting of a mix of directly-employed sales representatives and exclusive sales agents that are responsible for particular geographic regions of the country. Outside of the United States, our sales force consists of directly-employed sales representatives, independent sales agents and territory-based distributors. We believe that continuing to expand the range of such teams will allow us to increase our market share and drive adoption of our products and procedures.
- Provide Tailored Solutions in Response to Surgeon Needs. Responding quickly to the needs of spine surgeons, which we refer to as “Absolute Responsiveness”, is central to our corporate culture, critical to our success, and we believe differentiates us from our competition. We solicit information and feedback from our surgeon customers and clinical advisors regarding the utility of, and potential improvements to, our products. For example, we have an on-site machine shop to allow us to rapidly manufacture product prototypes and a state-of-the-art cadaver operating theatre

in San Diego, California to provide clinical training and validate new ideas through prototype testing. We also maintain regional training facilities and centers for excellence in strategic locations around the globe. Absolute Responsiveness goes beyond product development to include active support in all areas, including clinical research and payer relations. We believe that continuing to remain connected and responsive to the collective voices of the surgeon community will allow us to increase our market share and drive adoption of our procedurally-integrated spine solutions.

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- Selectively License or Acquire Complementary Products and Technologies and Drive our International Presence. In addition to building our company through internal product development and global expansion efforts, we intend to selectively license or acquire complementary products and technologies that we believe will keep us on the forefront of innovation and to pursue opportunities that allow us to expand our presence in emerging geographical opportunities. For example, following our acquisition of Ellipse Technologies, we now offer innovative products based on the MAGEC technology platform. With this acquisition, we accelerated our entry into the pediatric and idiopathic spine deformity segment and expanded our international presence. In addition, with our acquisition of the LessRay software technology suite, we will be able to help surgeons and hospital staff manage radiation exposure, without compromising intra-operative images or visual accuracy. By acquiring complementary products and executing on domestic and international footprint opportunities, like our acquisition of our exclusive distributor in Brazil, we believe we can leverage our expertise at bringing new products to market that are intended to improve patient outcomes, simplify or better integrate techniques, reduce hospitalization and rehabilitation times across the globe, and, as a result, reduce overall costs to the healthcare system and continue to grow our global presence.
- Provide Intraoperative Monitoring Capabilities. Monitoring the health of the nervous system during spinal surgery has been a key component of our strategy of product differentiation since early in our development. Over time, surgeon and hospital demand for nerve monitoring has increased along with the advancement of technologies and techniques used in IOM. We believe our proprietary NVM5 platform is a differentiator in the market and is unique in its ability to provide information about the directionality and proximity of nerves. Following our acquisition of Biotronic NeuroNetwork, we have expanded the scale of our IOM services business and are driving increased utilization of our NVM5 platform. We intend to continue to expand the utility of such platforms and broaden our IOM product and services offerings to further our value to our customers and increase adoption and usage.

Industry Background and Market

The spine is the core of the human skeleton, and provides a crucial balance between structural support and flexibility. It consists of 33 separate bones called vertebrae that are connected together by connective tissue (defined as bone, muscle, or ligament) to form a column and to permit a normal range of motion. The spinal cord, the body’s central nerve system, is enclosed within the spinal column. Vertebrae are paired into what are called motion segments that move by means of three joints: two facet joints and one spine disc. The four major categories of spine disorders are degenerative conditions, deformities, trauma and tumors. The largest market and the focus of our business historically are degenerative conditions of the facet joints and the intervertebral disc space. These two conditions can result in instability and pressure on the nerve roots as they exit the spinal column, causing back or neck pain or radiating pain in the arms or legs.

The prescribed treatment for back or neck pain depends on the severity and duration of the disorder. Initially, physicians will prescribe non-operative, conservative procedures including bed rest, medication, lifestyle modification, exercise, physical therapy, chiropractic care and steroid injections. In many cases, non-operative treatment options are effective; however, some patients eventually require spine fusion surgery. The vast majority of spine fusion surgeries are done using traditional open surgical techniques from either the front or back of the patient. These traditional open surgical approaches generally require a large incision in the patient’s abdomen or back in order to enable the surgeon to access and see the spine and surrounding area. These open procedures are invasive, lengthy and complex, and typically result in significant blood loss, extensive tissue damage and lengthy patient hospitalization and rehabilitation.

We believe the market for procedurally-integrated spine surgery solutions will continue to grow over the long term, and we also believe that our market share will increase, because of the following market dynamics:

- Demand for Surgical Alternatives with Less Tissue Disruption. As has been proven in other surgical markets, we anticipate the broader acceptance of surgical treatments with less tissue disruption and patient trauma will result in increased demand.

- Favorable Domestic Demographics. The population segment most likely to experience back pain is expected to increase as a result of aging “baby boomers” (people born between 1946 and 1965). We believe this large population segment will increasingly demand a quicker return to activities of daily living following surgery than prior generations.
- Access to Care in Emerging Markets. Healthcare reforms in many emerging markets are expanding access to treatments to a greater proportion of their populations, which we believe will continue to drive strong increases in demand for healthcare-related product volumes. Increasing economic affluence in key developing regions will further drive demand for healthcare treatments.

Although we believe that the market for procedurally-integrated spine surgery solutions will continue to grow over the long term, economic, political and regulatory influences are subjecting our industry to significant changes that may slow the growth rate of the spine surgery market.

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Surgical Alternatives with Less Tissue Disruption

The benefits of minimally invasive surgery procedures in other areas of orthopedics have significantly contributed to the strong and growing demand for surgical alternatives with less tissue disruption of the spine. Surgeons and hospitals seek spine procedures that result in fewer operative and postoperative complications and decreased patient hospitalization periods. At the same time, patients seek procedures that reduce trauma, allow for faster recovery times and result in more favorable clinical outcomes. Despite patient and doctor demands, the rate of adoption of alternative surgical procedures with less tissue disruption has been relatively slow with respect to the spine. Currently, the majority of spine surgery patients are treated with traditional open and invasive techniques.

We believe the principal factor contributing to spine surgeons' slow adoption of traditional minimally invasive spine alternatives has been inconsistent outcomes driven by the limited or lack of direct access to and visibility of the surgical anatomy, and the associated complex instruments that have been required to perform these procedures. Most traditional minimally invasive spine surgery systems do not allow the surgeon to directly view the spine and the relevant pathology point and, as such, provide only restrictive visualization through a camera system or endoscope, while also requiring the use of complex surgical techniques. In addition, most traditional minimally invasive spine surgery systems use complex or highly customized surgical instruments that require special training and the completion of a large number of trial cases before the surgeon becomes proficient using the system, which is an impediment and/or deterrent to their adoption.

Our Commercial Products

Our MAS platform allows surgeons to perform a wide range of minimally-disruptive spine procedures in all regions of the spine and from various surgical approaches, while overcoming the shortcomings of traditional minimally invasive spine surgical techniques. The MAS platform is designed to treat a wide range of spinal pathologies while accommodating a surgeon's preferred surgical technique. We believe our approach improves clinical results and should continue to drive an expanded number of minimally-disruptive procedures performed, lead the market movement away from open surgery and make less invasive techniques the standard of care in spine fusion and non-fusion surgery.

Our products facilitate minimally-disruptive applications of the following spine surgery procedures, among others:

- Lumbar and thoracic fusion procedures in which the surgeon approaches the spine through the patient's back, side or abdomen;
- Cervical fusion procedures for either the posterior occipito-cervico-thoracic region or the anterior cervical region; and
- Decompression, which is removal of a portion of bone or disc from over or under the nerve root to relieve pinching of the nerve.

Our MAS platform combines three product categories: our MaXcess retractors, our specialized implants and fixation products, and our nerve monitoring systems and service offerings that collectively enable surgeons to detect and navigate around nerves while directing customized access to the spine for implant delivery. Biologics are used to complement procedures by assisting in the bone healing process.

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