VARIAN MEDICAL SYSTEMS INC
Form 10-K
November 26, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
ýANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended September 28, 2018
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: 1-7598
VARIAN MEDICAL SYSTEMS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	94-2359345
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
3100 Hansen Way, Palo Alto, California	94304-1038
(Address of principal executive offices)	(Zip Code)

(650) 493-4000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $1 par value	New York Stock Exchange

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 ý No ¨
Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No ý
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 ý No ¨
Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ý 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 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 ý
Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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. (Check one):

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o	Smaller reporting company o
	Emerging growth company o

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

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

As of March 30, 2018, the last business day of Registrant's most recently completed second fiscal quarter, the aggregate market value of shares of Registrant's common stock held by non-affiliates of Registrant (based upon the closing sale price of such shares on the New York Stock Exchange on March 30, 2018) was $10,080,869,160. Shares of Registrant's common stock held by the Registrant's executive officers and directors and by each entity that owned 10% or more of Registrant's outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

At November 16, 2018, the number of shares of the Registrant's common stock outstanding was 91,116,439.

DOCUMENTS INCORPORATED BY REFERENCE

Definitive Proxy Statement for the Company's 2019 Annual Meeting of Stockholders—Part III of this Form 10 K

VARIAN MEDICAL SYSTEMS, INC.
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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report"), including the Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A"), contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, which provides a "safe harbor" for statements about future events, products and future financial performance that are based on the beliefs of, estimates made by and information currently available to the management of Varian Medical Systems, Inc. ("VMS") and its subsidiaries (collectively "we," "our," "Varian" or the "Company"). The outcome of the events described in these forward-looking statements is subject to risks and uncertainties. Actual results and the outcome or timing of certain events may differ significantly from those projected in these forward-looking statements due to the factors listed under Item 1A, "Risk Factors," MD&A and disclosed from time to time in our other filings with the Securities and Exchange Commission ("SEC"). For this purpose, statements concerning: growth strategies; industry or market segment outlook; market acceptance of or transition to new products or technology such as fixed field intensity-modulated radiation therapy, image-guided radiation therapy, stereotactic radiosurgery, volumetric modulated arc therapy, brachytherapy, software, treatment techniques, and proton therapy; growth drivers; future orders, revenues, operating expenses, tax rate, cash flows, backlog, earnings growth or other financial results; new and potential future tariffs or cross-border trade restrictions; and any statements using the terms "believe," "expect," "anticipate," "can," "should," "would," "could," "estimate," "may," "in "potential," and "possible" or similar statements are forward-looking statements that involve risks and uncertainties that could cause our actual results and the outcome and timing of certain events to differ materially from those projected or management's current expectations. By making forward-looking statements, we have not assumed any obligation to, and you should not expect us to, update or revise those statements because of new information, future events or otherwise.

PART I

Item 1. Business

Overview

We, Varian Medical Systems, Inc., are a Delaware corporation originally incorporated in 1948 as Varian Associates, Inc. We are the world's leading manufacturer of medical devices and software for treating cancer and other medical conditions with radiotherapy, stereotactic radiosurgery, stereotactic body radiotherapy, brachytherapy and proton therapy. Our vision is a world without fear of cancer. Our mission is to combine the ingenuity of people with the power of data and technology to achieve new victories against cancer. To meet this challenge, we offer comprehensive solutions for fighting cancer.

We have two reportable operating segments: Oncology Systems and Proton Solutions (formerly known as Varian Particle Therapy). The operating segments were determined based on how our Chief Executive Officer, who is our Chief Operating Decision Maker ("CODM"), views and evaluates our operations. The CODM allocates resources to and evaluates the financial performance of each operating segment primarily based on operating earnings.

The Americas region includes North America (primarily United States and Canada) and Latin America. The EMEA region includes Europe, Russia, the Middle East, India and Africa. The APAC region primarily includes East and Southeast Asia and Australia.

Our business is subject to various risks and uncertainties. You should carefully consider the factors described in Item 1A, "Risk Factors" in conjunction with the description of our business set forth below and the other information included in this Annual Report on Form 10-K.

Long-term growth and value creation strategy

We are focused on cancer care solutions and well-positioned to positively influence more and more patients globally every day by bringing smarter and simpler solutions to healthcare providers. Our long-term growth and value creation strategy is to transform our company from the global leader in radiation therapy (also referred to as radiotherapy) to be the global leader in multi-disciplinary, integrated cancer care solutions. We intend to leverage our deep customer relationships, human-centered design, scale and financial strength to selectively broaden our capabilities to help cancer patients. To achieve these long-term objectives, we are focused on driving growth through strengthening our

leadership in radiation therapy, extending our global footprint and expanding into other addressable markets.

Distribution

On January 28, 2017 (the "Distribution Date"), we completed the separation and distribution (the "Distribution") of Varex Imaging Corporation ("Varex"), our former Imaging Components business segment. On the Distribution Date, each of our

stockholders of record as of the close of business on January 20, 2017 (the "Record Date") received 0.4 of a share of Varex common stock for every one share of our common stock owned as of the Record Date. Varex is now an independent publicly traded company and is listed on The NASDAQ Global Select Market under the ticker symbol "VREX." Varian continues to trade on the New York Stock Exchange under the ticker symbol "VAR." See Note 2, "Discontinued Operations" of the Notes to the Consolidated Financial Statements.

Oncology Systems

Our Oncology Systems business designs, manufactures, sells and services hardware and software products for treating cancer with conventional radiotherapy, and advanced treatments such as fixed field intensity-modulated radiation therapy (“IMRT”), image-guided radiation therapy (“IGRT”), volumetric modulated arc therapy (“VMAT”), stereotactic radiosurgery (“SRS”), stereotactic body radiotherapy (“SBRT”) and brachytherapy as well as associated quality assurance equipment. Our software solutions also include informatics software for information management, clinical knowledge exchange, patient care management, practice management and decision-making support for comprehensive cancer clinics, radiotherapy centers and medical oncology practices.

Our hardware products include linear accelerators, brachytherapy afterloaders, treatment accessories, and quality assurance software; and our software products include information management, treatment planning, image processing, clinical knowledge exchange, patient care management, decision-making support and practice management software. Our products enable radiation oncology departments in hospitals and clinics to perform conventional radiotherapy treatments and advanced treatments such as IMRT, IGRT, VMAT, SRS and SBRT, as well as the treatment of patients using brachytherapy techniques, which involves the implementation or temporary insertion of radioactive sources. Our products are also used by surgeons and radiation oncologists to perform stereotactic radiosurgery. Our software products are also used in medical oncology departments to manage chemotherapy treatments. Our software products help improve physician engagement and clinical knowledge-sharing, patient care management and clinical practice management. Our worldwide customers include university research and community hospitals, private and government institutions, healthcare agencies, physicians’ offices, medical oncology practices, radiotherapy centers and cancer care clinics.

Proton Solutions

Our Proton Solutions business develops, designs, manufactures, sells and services products and systems for delivering proton therapy, another form of external beam therapy using proton beams, for the treatment of cancer. Although proton therapy has been in clinical use for more than four decades, it has not been widely deployed due to high capital cost. Our current focus is bringing our expertise in X-ray beam radiation therapy to proton therapy to improve its clinical utility and to reduce its cost of treatment per patient, so that it is more widely accepted and deployed.

Radiation Therapy and the Cancer Care Market

Radiotherapy is the use of certain types of focused energy to kill cancer cells, shrink tumors, and provide palliative treatment for symptoms such as pain. Occasionally, radiation can also be used to treat non-cancerous conditions such as arterio- venous malformations, keloids, or trigeminal neuralgia. Radiotherapy is commonly used either alone or in combination with surgery, chemotherapy or targeted drugs. One important advantage is that radiation has its greatest effect on replicating cells. Simply stated, radiation damages cellular genetic material (chromosomes), which interrupts cell replication and results in eventual cellular death. Since the need for replication is particularly critical to the survival of a cancer and since normal tissues are better able to repair such damage, radiation tends to disproportionately kill cancer cells. The clinical goal in radiation oncology is to deliver the highest possible radiation dose directly to the tumor to kill the cancerous cells while minimizing radiation exposure to surrounding healthy tissue in order to limit or avoid complications, side effects and secondary effects caused by the treatment. This goal has been the driving force in clinical care advancements in radiation oncology over the past two decades, from conventional radiotherapy to advanced forms of treatment such as IMRT, IGRT, VMAT, SRS, SBRT and proton therapy. With the advent of radiosurgery and stereotactic body radiotherapy, other mechanism of killing cells are also being explored, including how radiation may stimulate the immune response to fight cancer growth.

The process for delivering radiotherapy typically consists of examining the patient, planning the treatment, simulating and verifying the treatment plan, providing quality assurance for the equipment and software, carefully positioning the patient, delivering the treatment, verifying that the treatment was delivered correctly and recording the history and

results of the treatment. The team responsible for delivering the radiotherapy treatment generally is comprised of a physician specializing in radiation oncology, a medical physicist or dosimetrist for planning patient treatments, a medical physicist for conducting appropriate quality assurance procedures and a radiation therapist for positioning the patients for treatment and operating the machines.

The most common form of radiation oncology involves delivering X-ray beams from outside of the patient's body, a process sometimes referred to as external beam radiotherapy. A device called a medical linear accelerator generates the high-energy X-ray beams and delivers the radiation to the patient lying on a treatment couch. The linear accelerator rotates around a patient delivering the radiation beam that is conformed to the tumor shape from different angles. This concentrates radiation at the tumor while at the same time minimizing the dose delivered to the surrounding healthy tissue. Conventional radiotherapy typically involves multiple, or fractionated, treatments of a tumor in up to 50 treatment sessions. The linear accelerator may also deliver electron beams for the treatment of diseases closer to the body surface.

IMRT is an advanced form of external beam radiotherapy in which the shape and intensity of the radiation beams are varied optimally (modulated) across the target region. IMRT allows the radiation dose to be more precisely conformed to the volume of the tumor, allowing physicians to deliver higher doses of radiation to the tumor than conventional radiation treatments, while limiting radiation dose to nearby healthy tissue. In this way, clinicians can design and administer an individualized treatment plan for each patient, targeting the tumor within millimeters. IMRT can be used to treat head and neck, breast, prostate, pancreatic, lung, liver, gynecological and central nervous system cancers. IMRT has become a well-accepted standard of treatment for cancer, and every year additional treatment centers, from university hospitals to local community clinics, adopt IMRT for their treatments. We are a leading global provider of products that enable IMRT for the treatment of cancer.

VMAT is a significant further advancement in IMRT that allows physicians to control three parameters simultaneously: (i) the rate at which the linear accelerator gantry rotates around the patient, (ii) the beam-shaping aperture and (iii) the rate at which the radiation dose is delivered to the patient. This creates a finely-shaped IMRT dose distribution that more closely matches the size and shape of the tumor, with faster treatment times. Our RapidArc® radiotherapy products plan and deliver VMAT treatments.

Physicians, hospitals and clinics place additional value on radiotherapy equipment and treatments, such as VMAT, that enable shorter treatment times and greater patient throughput. From the patient's standpoint, reduced treatment times means that the patient is immobilized on the treatment couch for a shorter time period. Shorter treatment sessions decrease waiting times and, since treatments are delivered in fractions over the course of many days, can mean fewer disruptions to a patient's daily routine. From the physicians' and hospitals' standpoint, shorter treatment times can lessen the chance of tumors moving during treatment and can increase patient throughput. Shorter treatment times and increased patient throughput can increase the number of treatments per day (which is a particular concern in countries with lower numbers of treatment machines per capita), and, as a result, can decrease the cost per treatment which in turn can mean greater access to advanced care for more patients.

IGRT is another advanced form of external beam radiotherapy complementing IMRT to enhance treatments. While IMRT helps physicians more precisely conform the beam to the tumor, IGRT allows physicians to see how a tumor and normal tissue move or change during a course of treatment, thereby improving treatment accuracy. This allows clinicians to tighten the margin of certainty around the tumor and spare more of the surrounding healthy tissue, potentially improving outcomes. We believe IGRT has become an accepted standard for treatment in the radiation oncology community. Varian's latest state-of-the-art linear accelerator mandates that all fractions of radiation delivered have IGRT before the treatment is delivered.

SRS and SBRT, often collectively referred to as radiosurgery, are advanced ablative radiation treatment procedures performed in a small number of treatment sessions with high doses of radiation. Radiosurgery typically incorporates advanced image-guidance to focus many small beams of radiation from many orientations precisely on the target and to minimize the dose to surrounding normal tissues. Radiation oncologists, surgeons and other oncology specialists increasingly recognize radiosurgery as a useful tool to treat cancerous and non-cancerous lesions anywhere in the body.

An alternative to external beam radiotherapy, brachytherapy involves the insertion of radioactive seeds, wires or ribbons directly into a tumor or body cavity near the tumor. These techniques tend to irradiate much less surrounding healthy tissue so that physicians can prescribe a higher total dose of radiation, typically over a shorter period of time. Brachytherapy is often used for cancers of the head and neck, breast, uterus, cervix, soft tissue, skin and prostate.

Proton therapy is another form of external beam radiotherapy that uses proton particles beams generated with a cyclotron rather than X-ray beams from a linear accelerator. A proton beam's signature energy distribution curve, known as the "Bragg peak," allows for greater precision in targeting tumor cells with an even lower dose to nearby healthy tissue than may be delivered with X-ray beams from a linear accelerator. This makes proton therapy a preferred option for treating certain cancers, particularly cancers in children and tumors near critical structures such as the optic nerve. Pencil-beam scanning capability, which is an advanced way of delivering the proton beam, allows for greater sparing of healthy tissue compared to fan-beam scanning of the proton beam. Although proton therapy has been in clinical use for more than four decades, it has not been widely deployed due to its high capital cost and the market is still developing. We believe we can apply our experience in X-ray beam radiotherapy to proton therapy, reducing the cost of treatment per patient for existing clinical applications and expanding

the use of proton therapy into a broader array of cancer types. We believe that proton therapy will over time become a more widely accepted method of treatment.

The radiation oncology market is growing globally due to a number of factors. According to the American Institute of Cancer Research, there will be an estimated 18 million cancer cases diagnosed globally. Worldwide, the number of new cancer cases diagnosed annually is projected to increase from approximately 14 million in 2012 to almost 25 million by 2030, with most of the increase coming from low- and middle-income countries such as China and India, according to the September 2015 Lancet Oncology report compiled by the Global Task Force on Radiotherapy for Cancer Control. In addition, technological advancements have helped to improve the precision and applicability of radiotherapy and radiosurgery, potentially expanding the use of radiotherapy and radiosurgery equipment to treat a broader range of cases. Technological advances in hardware and software are also creating a market for replacing an aging installed base of machines that are unable to deliver new, higher standards of care.

The rise in cancer cases, together with the increase in sophistication of new treatment protocols, have created demand for more automated products that can be integrated into clinically practical systems to make treatments more rapid and cost effective. Technology advances leading to improvements in patient care, the availability of more advanced, automated and efficient clinical tools in radiation therapy, the advent of more precise forms of radiotherapy treatment (such as IMRT, IGRT, VMAT, SRS, SBRT, brachytherapy and proton therapy), and innovative new technology and equipment (such as EDGE™ and TrueBeam™) that enable treatments that reduce treatment times and increase patient throughput should drive the demand for our radiation therapy products and services.

International markets, in particular, are under-equipped to address the growing cancer incidence. Patients in many foreign countries must frequently endure long waits for radiotherapy. According to a peer-reviewed publication in the International Journal of Radiation Oncology Biology and Physics in 2014, radiotherapy is required in more than half of new cancer patients, particularly in low- and middle-income countries, and according to an article published in Seminars in Radiation Oncology in 2017, it is estimated that more than 12,000 additional treatment machines will be required by 2035 in these countries alone. For example, China, India and Brazil are estimated to require over 3,800, 1,200 and 400 additional machines, respectively, by 2035. The ever-increasing incidences of cancer and the demand for additional treatment machines in these regions represent additional drivers for our continued growth in international markets.

Products

Oncology Systems

Our Oncology Systems business is the leading provider of advanced hardware and software products for treatment of cancer with conventional radiation therapy, and advanced treatments such as IMRT, IGRT, VMAT, SRS, SBRT and brachytherapy. Oncology Systems products address each major aspect of the radiotherapy process, including linear accelerators and accessory products for positioning the patient and delivering the X-ray beam; brachytherapy afterloaders for delivering radioactive implantable seeds; treatment planning software for planning treatment sessions and dose delivery; treatment accessories and quality assurance software for simulating and verifying treatment plans before treatment as well as verification of correct treatment delivery; and information management software for recording the history and results of treatments and other patient treatment information and data, including patient images.

The focus of our Oncology Systems business is addressing the key concerns of the market for advanced cancer care systems; improving efficiency, precision, cost-effectiveness and ease of delivery of these treatments; and providing greater access to advanced treatments. A core element of our business strategy is to provide our customers with highly versatile, proven products that are interoperable and can be configured and integrated into automated systems that combine greater precision, shorter treatment times and greater cost effectiveness and that improve the entire process of treating a patient. Our products and accessories for IMRT and IGRT allow clinicians to track and treat tumors using very precisely shaped beams, targeting the tumor as closely as currently possible and allowing the delivery of higher doses of radiation to the tumor while limiting exposure of nearby healthy tissue. Additionally, the precision and versatility of our products and technology make it possible to use radiotherapy to treat metastatic cancers. With our treatment planning, verification and information management software products, a patient’s treatment plans, treatment data and images are recorded and stored in a single database shared by each of our products, which enables better

communication among products. Our products also allow multiple medical specialties - radiation oncology, neurosurgery, diagnostic radiology and medical oncology, as well as clinicians in multiple locations - to share equipment, resources and information in a more efficient, cost-effective manner. Furthermore, the ability of our products and technology to interoperate with each other and to interconnect into automated systems allows physicians to schedule and treat more patients within a set time period, which adds to the cost-effectiveness of our equipment.

Medical linear accelerators are the core device for delivering conventional external beam radiotherapy, IMRT, IGRT, VMAT, SRS and SBRT, and we produce versions of these devices to suit various clinical requirements. In May 2017, we introduced our Halcyon™ treatment system, our newest device for cancer treatment. We received a CE mark for the Halcyon system in May 2017 and FDA 510(k) clearance in June 2017. The Halcyon system has been designed on a platform of next generation technology including a full field ring gantry design that rotates at four times per minute, an innovative stacked and staggered multi-leaf collimator design, virtually silent magnetic drive motors and solid-state modulators. This new platform is the smallest footprint linear accelerator in our portfolio, uses less energy, and has been designed with a human centered user experience concept that benefits the patient and the health care practitioner for simplicity of treatment and use. At the high end of our accelerator product line portfolio, the TrueBeam and EDGE systems for image-guided radiotherapy and radiosurgery are fully-integrated high-energy systems designed from the ground up to treat a moving target with higher speed and accuracy. The Clinac® iX linear accelerators deliver high-energy X-ray beams and are designed for more streamlined and advanced treatment processes, including IMRT and IGRT. We also produce the Trilogy™ linear accelerator, designed to be a versatile, cost-effective, precise high-energy device with a faster dose delivery rate and more precise isocenter compared to the Clinac iX. Our UNIQUE™ medical linear accelerator is a low-energy linear accelerator for the more price sensitive emerging markets, designed to meet the evolving needs of our IMRT and IGRT customers in these markets.

Our Millennium™ series of multi-leaf collimators and High Definition 120 (“HD 120”) multi-leaf collimators are used with a linear accelerator to define the size, shape and intensity of the generated beams. PortalVision™, our electronic portal-imager, is used to verify a patient’s position while on the treatment couch, which is critical for accurate treatments and simplifies quality assurance of individual treatment plans. We also offer an innovative real-time patient position monitoring product, the RPM™ respiratory gating system, which allows the linear accelerator to be synchronized with patient breathing to help compensate for tumor motion during treatment. In addition, we manufacture the Calypso® system (some features not approved for use in all markets), which can continuously track and monitor the position of implanted or surface-attached Beacon® transponders. This technology allows the clinician to easily locate the position of the tumor and aim the treatment beam precisely to deliver the full, prescribed dose to the tumor, and minimize exposure of surrounding healthy tissues.

We also offer the EDGE radiosurgery suite, a combination of products for performing advanced radiosurgery using new real-time tumor tracking technology and motion management capabilities. The EDGE radiosurgery suite includes the EDGE radiosurgery accelerator and the Calypso System with Dynamic Edge™ Gating, and the PerfectPitch™ Couch with six degrees of freedom to accurately and precisely align the patient position. Our IGRT accessories include the On-Board Imager® (“OBI”) hardware accessory affixed to the linear accelerator that allows dynamic, real-time imaging of tumors while the patient is on the treatment couch and offers cone-beam computerized tomography (“CBCT”) imaging software capability to allow patient positioning based on soft-tissue anatomy. Using sophisticated image analysis tools, the CBCT scan can be compared with a reference CT scan taken previously to determine how the treatment couch should be adjusted to fine-tune and verify the patient’s treatment setup and positioning prior to delivery of the radiation. To deliver the most advanced forms of IGRT, our accelerators would typically have an OBI, CBCT, PortalVision and other IGRT-related hardware and software as accessories.

Our RapidArc radiotherapy products are a proprietary implementation of VMAT that coordinate beam shaping, dose rate and gantry speed to deliver a highly conformal dose distribution to the target tumor. RapidArc products enable the planning and delivery of image-guided IMRT in a single continuous rotation of up to 360 degrees rather than as a series of fixed fields. Our RapidArc products enable faster delivery of radiation treatment with the possibility of reduced opportunity for tumor movement during treatment, as well as greater patient throughput and lower cost per patient for the hospital or clinic. We believe RapidArc represents a significant advancement in IMRT cancer treatment.

Our HyperArc™ High-Definition Radiotherapy product is designed to simplify, automate and improve the quality of intracranial SRS, making SRS accessible to more clinics and patients around the world. HyperArc received a CE mark in August 2017 and FDA 510(k) clearance in September 2017 and is currently available for sale in the United States and other global markets where a CE mark is applicable. We expect that HyperArc will significantly improve the quality and efficiency of sophisticated SRS procedures. HyperArc is available only on the TrueBeam and Edge

platforms.

During fiscal year 2018, we further expanded our product offerings through business acquisitions. We purchased Mobius Medical Systems ("Mobius") in February 2018. Mobius markets and sells quality assurance products to radiation oncology departments around the globe. We will continue to sell those products while expanding and integrating the technology for current and future applications. In July 2018, we acquired humediQ GmbH, which markets and sells the IDENTIFY ™ products that enable patient and accessory verification, patient setup position, and motion monitoring for radiation oncology treatments. We will continue to market and sell these product as we expand the regulatory clearance footprint around the globe and enhance and integrate the technology for current and future applications.

Our software products enhance and enable the delivery of advanced radiotherapy treatments, from the initial treatment planning and plan quality assurance verification to the post-treatment recording of data and storing of patient information, as well as help improve physician engagement and clinical knowledge-sharing, patient care management and clinical practice management of cancer clinics, radiotherapy centers and oncology practices for better performance. Prior to any treatment, physicians must prescribe, or plan, the course of radiation delivery for the patient. We offer a range of treatment planning products that assist physicians in designing this treatment plan. Our Eclipse™ treatment planning system provides physicians with 3D image viewing, treatment simulation, radiation dosage calculation and verification and other tools for generating treatment delivery plans for the patient. The Eclipse software utilizes a sophisticated technique known as inverse planning to enable physicians to rapidly develop optimal treatment plans based on a desired radiation dose outcome to the tumor and surrounding tissue. Our RapidPlan™ Knowledge-based Planning tool creates a new category for artificial intelligence applied to treatment planning systems in which machine learned statistical models can be used to predict the achievable quality of an IMRT treatment from a patient's anatomy. RapidPlan is designed to streamline the planning process by using shared clinical knowledge embedded in its statistical plan models. Clinics may use plan models included with Eclipse or can create models based on their own treatment methods and protocols.

We continue to enhance our treatment planning software products and have integrated multi-criteria optimization radiotherapy treatment planning algorithms licensed from the Fraunhofer Institute that enable clinicians to quickly navigate solution space to find the ideal treatment plan for each patient. We have incorporated this technology along with other treatment planning software tools to enhance both treatment planning efficiency and quality.

Our software product offerings also include Varian Treatment™, which connects ARIA® Oncology Information Management System ("ARIA") to third party linear accelerators and expands our software support of third party manufacturers. The ARIA information system is a comprehensive real-time information management system and database that records and verifies radiotherapy treatments carried out on the linear accelerator, records and stores patient data relating to radiation therapy treatments (as well as chemotherapy treatment which may be also prescribed by a physician), performs patient charting and manages patient information and patient image data. This gives clinics and hospitals the ability to manage treatment and patient information across radiation oncology and medical oncology procedures. Also, because ARIA is an electronic medical record, it can enable users to operate filmless and paperless oncology departments and cancer clinics. ARIA is a (ONC-Health IT) 2015 Edition Health IT Module and supports the ICD-10 billing codes. Our FullScale™ oncology-specific information technology solutions take advantage of virtualization or cloud technologies to deploy our ARIA oncology information and Eclipse treatment planning systems in a way that enables treatment centers to take advantage of economies of scale. We have from time to time entered into agreements with a variety of companies to increase the capabilities of our ARIA Information Systems software.

Our Insightive™ analytics software solution aggregates clinical and operational data and allows for improved decision making and practice management. Insightive enables oncology administrators and clinicians to use real-time information to discover patterns and trends through interactive dashboards and visualizations. We also created an interactive online group on the OncoPeer™ platform for clinicians to share knowledge-based cancer treatment models that can improve the efficiency and quality of cancer care across multiple institutions. The OncoPeer cloud community is a platform where oncologists, clinicians and other oncology professionals can publish knowledge, share data, exchange treatment techniques and discuss best practices within a professional oncology network.

Our Velocity™ software provides solutions at the clinical process level to aggregate unstructured treatment and imaging data from diverse systems. It allows for a more comprehensive view of a patient's diagnostic imaging and treatment history and helps clinicians make more informed treatment decisions.

360 Oncology™ is a care management platform designed to integrate and coordinate key elements of cancer care, so patients and their cancer teams can collaborate on achieving the best outcomes. In a single platform, 360 Oncology brings together radiation, medical and surgical oncology, social services, primary care physicians, as well as the patient, to facilitate true collaborative and coordinated care. It enables tumor boards to more effectively coordinate patient care among the numerous specialists involved in cancer treatment. With Varian 360 Oncology care management, a clinic's data, records and patient information are connected through a single platform, enabling the entire cancer-fighting team to coordinate care.

Qumulate™ is our cloud-based software technology that collects and analyzes machine performance data in a radiation therapy department and allows users to compare their machine performance data and trends against a community of users' data.

In addition to offering our own suite of equipment and software products for planning and delivering radiotherapy treatments, we have partnered with selected leaders in certain segments of the radiation therapy and radiosurgery market. In October 2016, we established a three-year strategic agreement with McKesson to supply its US Oncology Network and Vantage Oncology

affiliated sites of care with treatment delivery systems and planning, service and radiotherapy information system solutions. Under the agreement, we are collaborating with McKesson to establish interoperability between our Aria product and McKesson IT solutions which we anticipate will facilitate access to Aria, Eclipse and Velocity at its sites that do not currently utilize these solutions. We have a partnership agreement with Siemens AG ("Siemens") through which, among other things, we represent Siemens diagnostic imaging products to radiation oncology clinics in the US and agreed upon countries, and Siemens, represents our equipment and software products for radiotherapy and radiosurgery to its healthcare customers in agreed upon countries. Furthermore, we and Siemens have developed interfaces to enable ARIA and Eclipse to connect with Siemens linear accelerators and imaging systems, and are exploring opportunities to co-develop new imaging and treatment solutions. We have equity investments which include Grail, Inc., a life sciences company developing blood tests for early-stage cancer detection and Fusion Pharmaceuticals Inc., a clinical stage company focused on developing targeted alpha-particle radiotherapeutics for the treatment of cancer.

Our brachytherapy operations design, manufacture, sell and service advanced brachytherapy products, including VariSource™ HDR afterloaders and GammaMed™ HDR/PDR afterloaders, BrachyVision™ brachytherapy treatment planning system, applicators and accessories. Brachytherapy also develops and markets the VariSeed™ LDR prostate treatment planning system and the Vitesse™ software for real-time treatment planning for HDR prostate brachytherapy. In October 2018, we introduced a new brachytherapy afterloader system, Bravos™. We received CE mark for Bravos in July 2018 and FDA 510(k) clearance in October 2018, and Bravos is currently available for shipment in 86 CE mark countries. Varian has filed for the Sealed Source Device registration required in the United States before shipment may ensue. Bravos is an integrated system designed to improve the patient and clinic experience by simplifying brachytherapy treatment and providing greater workflow efficiency. It is compatible with our full range of applicators and integrates with our Brachyvision for treatment planning. The ARIA oncology information system coordinates care from end to end, scheduling appointments, orchestrating the clinical workflow, delivering the plan to the afterloader, updating the patient's electronic record, and capturing clinical data for analytics.

For a discussion of Oncology Systems business segment financial information, see Note 17, "Segment Information" of the Notes to the Consolidated Financial Statements.

Proton Solutions

Our Proton Solutions business develops, designs, manufactures, sells and services products and systems for delivering proton therapy, another form of external beam therapy using proton beams, for the treatment of cancer. Our ProBeam® system is capable of delivering precise intensity modulated proton therapy ("IMPT") using pencil beam scanning technology. ProBeam Compact is our lower cost, single room proton therapy product launched in fiscal year 2014. During fiscal year 2016, we booked our first ProBeam Compact order. In October 2018, we introduced ProBeam 360°, our new single-room proton therapy system, with 30 percent smaller footprint and 25 percent lower vault construction costs as compared to ProBeam Compact. The new system has a 360-degree rotating gantry, iterative cone-beam CT imaging and high-definition pencil-beam scanning technology. The system can also provide a viable path to potential next generation treatments. Proton therapy is a preferred option for treating certain cancers, particularly tumors near critical structures such as the optic nerve and pediatric cancers. Although proton therapy has been in clinical use for more than four decades, it has not been widely deployed due to high capital cost. Proton therapy facilities are large-scale construction projects that are time consuming, involve significant customer investment and often complex project financing. Our proton therapy systems are currently in operation in ten sites worldwide.

During fiscal years 2018, 2017 and 2016, we recorded two, six and two proton therapy orders, respectively.

In limited cases, we participate, along with other investors and at market terms, in the financing of proton therapy centers. See Note 16, "Proton Solutions Loans and Investment" of the Notes to the Consolidated Financial Statements for further discussion on our Proton Solutions financing arrangements.

For a discussion of segment financial information, see Note 17, "Segment Information" of the Notes to the Consolidated Financial Statements.

Marketing and Sales

We employ a combination of direct sales forces and independent distributors or resellers for the marketing and sales of our products worldwide. Our gross orders and revenues reflect a growing percentage coming from international regions and particularly emerging markets. As a U.S.-based company, the competitiveness of our product pricing is influenced by the fluctuation of the U.S. Dollar against other currencies. A stronger U.S. Dollar against foreign currencies would make our

product pricing more expensive and less competitive compared to products sold in non-U.S. Dollar currencies. A stronger U.S. Dollar against foreign currencies would also lower our international revenues and gross orders when measured in U.S. Dollars. These conditions affected our business and demand for our products in the first half of fiscal year 2016. In fiscal years 2018, 2017 and 2016, we did not have a single customer that represented 10% or more of our total revenues.

Oncology Systems

Our Oncology Systems business sells direct in the United States and Canada and uses a combination of direct sales and independent distributors in international regions.

Through our strategic global partnership with Siemens, we represent Siemens diagnostic imaging products to radiation oncology clinics in most global markets. Siemens represents our equipment and software products for radiotherapy and radiosurgery to its healthcare customers in agreed upon countries. We sell our Oncology Systems products primarily to university research and community hospitals, private and governmental institutions, healthcare agencies, physicians' offices and cancer care clinics worldwide. These hospitals, institutes, agencies, physicians' offices and clinics replace equipment and upgrade treatment capability as technology evolves. Sales cycles for our external beam radiotherapy products typically can be quite lengthy since many of them are considered capital equipment and are affected by budgeting cycles. Our customers frequently fix capital budgets one or more years in advance. In recent years, we have seen the purchasing cycle lengthen as a result of the more complex decision-making process associated with larger dollar value transactions for more sophisticated IGRT and surgical equipment, and other technical advances.

During an economic downturn, we would expect to see customers' decision-making process further complicated and lengthened, which may cause hospitals, clinics and research institutions to more closely scrutinize and prioritize their capital spending in light of tightened capital budgets, tougher credit requirements, the general constriction in credit availability, and consolidation of providers. In addition, the last economic downturn caused customers to delay requested delivery dates, increasing the average order to revenue conversion cycle. Historically, this conversion cycle has been longer when new products are introduced or when we sell more products internationally. The lengthening of our order to revenue conversion cycle could reduce our revenues and margins. In addition, the same factors impacting the order to revenue conversion cycle may extend the receivables collection cycle and potentially increase bad debts.

Over the last few years, we have seen a greater percentage of Oncology Systems gross orders and revenues come from international markets, within which certain emerging markets often have lower gross margins and longer installation cycles since many of these purchases are for new sites where treatment vaults need to be constructed. We have also seen an increased portion of gross orders and revenues coming from services and software licenses, both of which have higher gross margin percentages than our hardware products. We have also been investing a higher portion of our Oncology Systems research and development expenses in software and software-related products.

The radiation oncology market in North America is largely characterized by replacements of older machines, with periodic increases in demand driven by the introduction of new technologies. Reimbursement rates in the United States have generally supported a favorable return on investment for the purchase of new radiotherapy equipment and technologies. While we believe that improved product functionality, greater cost-effectiveness and prospects for better clinical outcomes with new capabilities such as IMRT, IGRT and VMAT tend to drive demand for radiotherapy products, large changes in reimbursement rates or reimbursement structure can affect customer demand and cause market shifts. We believe that growth of the radiation oncology market in the United States could be impacted as customers' decision-making processes are complicated by the uncertainties surrounding the medical device excise tax, as defined below under "Medicare and Medicaid Reimbursement," and reimbursement rates for radiotherapy and radiosurgery, and that this uncertainty will likely continue in future fiscal years. We believe this uncertainty could impact transaction size, timing and purchasing processes, and also contribute to increased quarterly business variability.

For a discussion of financial information about geographic areas, see Note 17, "Segment Information" of the Notes to the Consolidated Financial Statements and MD&A.

Proton Solutions

Our Proton Solutions business primarily uses direct sales specialists who collaborate with our Oncology Systems sales group globally on customer projects. Potential customers are government-sponsored hospitals and research institutions and research universities, which typically purchase products through public tenders, as well as private hospitals, clinics and private developers. While this market is still developing and can be highly variable, there has been significant growth in this market over the last several years and we believe that growth in this business will continue in the major metropolitan areas in the

United States and abroad, driven by institutions that wish to expand their clinical offerings and increase their profile in their respective communities. We are investing substantial resources to grow this business. Proton therapy facilities are large-scale construction projects that are time consuming and involve significant customer investment and often complex project financing. Consequently, this business is vulnerable to general economic and market conditions, as well as reimbursement rates. Customer decision-making cycles tend to be very long, and orders generally involve many contingencies. While credit markets have improved in recent years, the funding environment for large capital projects, such as proton therapy projects, remains constrained.

Backlog

Backlog is the accumulation of all gross orders for which revenues have not been recognized but are still considered valid. Backlog is stated at historical foreign currency exchange rates and revenue is released from backlog at current exchange rates, with any difference recorded as a backlog adjustment. Orders may be revised or canceled, as customers' needs change and as our new products become available; consequently, it is difficult to predict with certainty the amount and timing of when backlog will result in revenues. Our backlog at the end of fiscal year 2018 was $3.2 billion, of which we expect to recognize approximately 45% as revenues in fiscal year 2019. Our backlog at the end of fiscal year 2017, was $3.1 billion, of which approximately $1.5 billion was recognized as revenues in fiscal year 2018. Our Oncology Systems backlog represented 93% and 90% of the total backlog at the end of fiscal years 2018 and 2017, respectively.

Gross orders are defined as new orders recorded during the period and revisions to previously recorded orders. New orders are recorded for the total contractual amount, excluding certain pass-through items and service items which are recognized as the revenue is recognized, once a written agreement for the delivery of goods or provision of services is in place and, other than Proton Solutions, when shipment of the product is expected to occur within two years, so long as any contingencies are deemed perfunctory. For our Proton Solutions business, we record orders when construction of the related proton therapy treatment center is reasonably expected to start within two years, but only if any contingencies are deemed perfunctory. We will not record Proton Solutions orders if there are major financing contingencies, if a substantial portion of the financing for the project is not reasonably assured or if customer board approval contingencies are pending. We perform a quarterly review to verify that outstanding orders remain valid. Aged orders that are not expected to ultimately convert to revenues are deemed dormant and are reflected as a reduction in the backlog amounts in the period identified. If an order is no longer expected to be converted to revenue, we record a backlog adjustment which reduces backlog but does not impact gross orders for the period.

Backlog adjustments are comprised of dormancies, cancellations, foreign currency exchange rate adjustments, backlog acquired from our acquisitions, and other adjustments. Gross orders do not include backlog adjustments. In fiscal years 2018, 2017 and 2016, our backlog adjustments were a reduction of $152.8 million, $154.5 million and $189.8 million, respectively.

Competition

The markets for cancer treatment are characterized by rapidly evolving technology, intense competition and pricing pressure. We compete with companies worldwide, some of whom may have greater financial, marketing and other resources. Large amounts of resources are being invested in the research and development of new therapies for cancer. The successful development of alternative therapies for cancer, for example, immunotherapy, increased efficacy of new therapies or existing products, pricing decisions by competitors and the rate of market penetration by competitive products may render our products obsolete or noncompetitive.

Our smaller competitors could be acquired by companies with greater financial strength, which could enable them to compete more aggressively. Some of our suppliers or distributors could also be acquired by competitors, which could disrupt these supply or distribution arrangements and result in less predictable and reduced revenues. New competitors and new technologies, such as radiosurgery, VMAT, MR-Linac and proton therapy, will compete directly with our products or will compete for customer budget allocation. We have directed substantial product development efforts into (i) increasing the interconnectivity of our products for more seamless operation within a system, (ii) enhancing the ease of use of our software products and (iii) reducing setup and treatment times and increasing patient throughput. We have also maintained an "open systems" approach that allows customers to "mix and match" our various individual products, incorporate products from other manufacturers, share information with other systems or products and use the

equipment for offering various methods of radiation therapy treatment. We have done this based on our belief that such interconnectivity will increase the acceptance and adoption of IMRT, IGRT and VMAT and will stimulate demand for our products. There are competitive “closed-ended” dedicated-use systems, however, that place simplicity of use ahead of flexibility. If we have misjudged the importance to our customers of maintaining an “open systems” approach, or if we are unsuccessful in our efforts to sustain interconnectivity, enhance ease-of-use and reduce setup and treatment times, our revenues could suffer.

Our Oncology Systems customers' equipment purchase considerations typically include: reliability, servicing, patient throughput, precision, price, payment terms, connectivity, clinical features, the ability to track patient referral patterns, long-term relationship and capabilities of customers' existing equipment. We believe we compete favorably with our competitors based upon our strategy of providing a complete package solution of products and services in the field of radiation oncology and our continued commitment to global distribution and customer services, value-added manufacturing, technological leadership and new product innovation. To compete successfully, we must provide technically superior, clinically proven products that deliver more precise, cost effective, high quality clinical outcomes, together in a complete package of products and services, and do so ahead of our competitors. Since our Oncology Systems products are generally sold on a basis of total value to the customer, our business may suffer when purchase decisions are based solely upon price, which can happen if hospitals and clinics give purchasing decision authority to group purchasing organizations. Further, competitors may delay customer purchasing decisions as customers evaluate competitive product offerings, potentially extending our sales cycle and adversely affecting our gross orders.

We are the leading provider of medical linear accelerators and related accessories. In radiotherapy and radiosurgery markets, we compete primarily with Elekta AB and Accuray Incorporated. Additionally, Elekta AB and ViewRay Incorporated have announced the introduction of MR-Linac devices that also compete with us for hospital budget allocations. Sun Nuclear Corporation and Standard Imaging have QA products that compete with our Mobius and Qumulate offerings. Vision RT, Brainlab and C-RAD have competing products with our humediQ product line in the areas of patient monitoring and tracking during therapy. With our information and image management, simulation, treatment planning and radiosurgery products, we also compete with a variety of companies, such as Philips Medical Systems, RaySearch Laboratories AB, Brainlab AG and Best Theratronics, Ltd. We also encounter some competition from providers of enterprise hospital information systems. With respect to our brachytherapy solutions, our competitors are Elekta AB, MIM Software Inc. and Eckert & Ziegler BEBIG GmbH. In our Oncology Systems service and maintenance business, we compete with independent service organizations and our customers' internal service organizations.

In addition, as a radiotherapy and radiosurgery equipment provider, we also face competition from other cancer treatment alternatives, such as traditional surgery, chemotherapy, robotic surgery and drug therapies, among others. To compete successfully, we need to demonstrate and convince our customers and cancer patients of the advantages of radiation therapy over or in addition to other cancer treatment alternatives. This may involve funding and, in some instances, sponsoring clinical research and studies relating to the efficacy, comparative effectiveness and safety of radiation therapy as compared to such other alternative treatments.

In our 360 Oncology business for Oncology Systems segment, we compete with Elekta AB and large EMR companies such as EPIC and CERNER, as well as multiple new competing products from established companies such as Roche (Navify and Flatiron), Philips etc., and emerging competitors such as Carevive and Syapse.

The market for proton therapy products is still developing and is characterized by rapidly evolving technology, high competition and pricing pressure. Our ability to compete successfully depends, in part, on our ability to lower our product costs, and develop and provide technically superior, clinically proven products that deliver more precise, cost-effective, high quality clinical outcomes, including integration of IGRT technologies such as integrated volumetric imaging. In the proton therapy market, we compete principally with Hitachi Heavy Industries, Ion Beam Applications S.A., and Mevion Medical Systems, Inc. There are a number of smaller competitors that are also developing proton therapy products. We are the only established company in the field of radiation therapy to enter the particle therapy market directly.

Customer Services and Support

We warrant most of our Oncology Systems products for parts and labor for 12 months, and we offer a variety of post-warranty equipment service contracts and software support contracts to suit customers' requirements. Our domestic service centers are in Atlanta, Georgia; Las Vegas, Nevada; and Milpitas, California. Our international service centers are in Australia, Austria, Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, Hungary, India, Italy, Japan, Malaysia, the Netherlands, Russia, Saudi Arabia, Singapore, South Korea, Spain, Switzerland, Thailand, United Arab Emirates, and the United Kingdom. We also have field service personnel

throughout the world for Oncology Systems customer support services. Key Oncology Systems education operations are located in Beijing, China; Cham, Switzerland; Las Vegas, Nevada; Mumbai, India; and Tokyo, Japan; Montreal, Canada. Our network of service engineers and customer support specialists provide installation, warranty, repair, training and support services, project management, site planning, and professional services. We also have a distributed service parts network of regional hubs and forward-stocking locations across all major geographic areas. We generate service revenues by providing our customers with time-and-materials services, replacement part sales, post-warranty equipment service contracts and software support contracts. Most of the field service engineers are our employees, but our

products are serviced by employees of distributors and/or agents in a few foreign countries. Customers can access our extensive service network by calling any of our service centers.

We believe customer service and support are an integral part of our Oncology Systems competitive strategy. Growth in our service revenues has resulted from the increasing customer adoption of service contracts as the sophistication and installed base of our products increase. We also believe superior service plays an important role in marketing and selling medical products and systems, particularly as the products become more complex. Nevertheless, some of our customers use their own internal biomedical engineering organizations and/or independent service organizations to service equipment after the warranty period expires and therefore do not enter into agreements with us for extended service.

In the Proton Solutions business, we sell our proton therapy equipment generally with a 12-month warranty. Upon transfer of a treatment room to a customer, we generally begin generating service revenues by providing on-site proton therapy system technical operation and maintenance support services, which typically are for relatively long-term periods (e.g., a five-year term or longer). We believe customer service a