

WATERS CORP /DE/
Form 10-K/A
March 01, 2019
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2018

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**
Commission File Number: 01-14010

Waters Corporation

(Exact name of registrant as specified in its charter)

Delaware
*(State or other jurisdiction of
incorporation or organization)*

13-3668640
*(I.R.S. Employer
Identification No.)*

34 Maple Street

Milford, Massachusetts 01757

(Address, including zip code, of principal executive offices)

(508) 478-2000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: Common Stock, par value \$0.01 per share
Name of each exchange on which registered: New York Stock Exchange, Inc.
Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§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, a smaller reporting company, or 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 Accelerated filer Non-accelerated filer Smaller reporting company
Emerging growth company

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

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

State the aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2018: \$14,912,684,699.

Indicate the number of shares outstanding of the registrant's common stock as of February 22, 2019: 71,512,391

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement that will be filed for the 2019 Annual Meeting of Stockholders are incorporated by reference in Part III.

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EXPLANATORY NOTE

On February 26, 2019, Waters Corporation (the Company) filed its Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (the Original Form 10-K). This Amendment No. 1 (the Amendment) amends the Original 10-K to correct a typographical error in Part II Item 8, Financial Statements and Supplementary Data, to remove the brackets on the 2018 increase in other liabilities on the Consolidated Statements of Cash Flows appearing on page 55.

Except as stated above, this Amendment does not amend any other information set forth in the Original Form 10-K.

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WATERS CORPORATION AND SUBSIDIARIES

ANNUAL REPORT ON FORM 10-K

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General**

Waters Corporation (the Company, we, our, or us) is a specialty measurement company that operates with a fundamental underlying purpose to advance the science that enables our customers to enhance human health and well-being. The Company has pioneered analytical workflow solutions involving liquid chromatography, mass spectrometry and thermal analysis innovations serving the life, materials and food sciences for more than 60 years. The Company primarily designs, manufactures, sells and services high performance liquid chromatography (HPLC), ultra performance liquid chromatography (UPLC™) and together with HPLC, referred to as LC) and mass spectrometry (MS) technology systems and support products, including chromatography columns, other consumable products and comprehensive post-warranty service plans. These systems are complementary products that are frequently employed together (LC-MS) and sold as integrated instrument systems using common software platforms. In addition, the Company designs, manufactures, sells and services thermal analysis, rheometry and calorimetry instruments through its TA™ product line. The Company is also a developer and supplier of advanced software-based products that interface with the Company's instruments, as well as other manufacturers' instruments.

The Company's products are used by pharmaceutical, biochemical, industrial, nutritional safety, environmental, academic and governmental customers working in research and development, quality assurance and other laboratory applications. LC is a standard technique and is utilized in a broad range of industries to detect, identify, monitor and measure the chemical, physical and biological composition of materials, and to purify a full range of compounds. MS technology, principally in conjunction with chromatography, is employed in drug discovery and development, including clinical trial testing, the analysis of proteins in disease processes (known as proteomics), nutritional safety analysis and environmental testing. LC-MS instruments combine a liquid phase sample introduction and separation system with mass spectrometric compound identification and quantification. The Company's thermal analysis, rheometry and calorimetry instruments are used in predicting the suitability and stability of fine chemicals, pharmaceuticals, water, polymers, metals and viscous liquids for various industrial, consumer goods and healthcare products, as well as for life science research.

Waters Corporation, organized as a Delaware corporation in 1991, is a holding company that owns all of the outstanding common stock of Waters Technologies Corporation, its operating subsidiary. Waters Corporation became a publicly-traded company with its initial public offering (IPO) in November 1995. Since the IPO, the Company has added two significant and complementary technologies to its range of products with the acquisitions of TA Instruments in May 1996 and Micromass Limited in September 1997.

Business Segments

The Company's business activities, for which discrete financial information is available, are regularly reviewed and evaluated by the chief operating decision maker. As a result of this evaluation, the Company determined that it has two operating segments: Waters™ and TA™. The Waters operating segment is primarily in the business of designing, manufacturing, selling and servicing LC and MS instrument systems, columns and other precision chemistry consumables that can be integrated and used along with other analytical instruments. The TA operating segment is primarily in the business of designing, manufacturing, selling and servicing thermal analysis, rheometry and calorimetry instruments. The Company's two operating segments have similar economic characteristics; product processes; products and services; types and classes of customers; methods of distribution; and regulatory environments. Because of these similarities, the two segments have been aggregated into one reporting segment for financial statement purposes.

Information concerning revenues and long-lived assets attributable to each of the Company's products, services and geographic areas is set forth in Note 17 in the Notes to the Consolidated Financial Statements, which is incorporated herein by reference.

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Waters Products and Markets

High Performance and Ultra Performance Liquid Chromatography

HPLC is a standard technique used to identify and analyze the constituent components of a variety of chemicals and other materials. The Company believes that HPLC's performance capabilities enable it to separate, identify and quantify a high proportion of all known chemicals. As a result, HPLC is used to analyze substances in a wide variety of industries for research and development purposes, quality control and process engineering applications.

The most significant end-use markets for HPLC are those served by the pharmaceutical and life science industries. In these markets, HPLC is used extensively to understand diseases, identify new drugs, develop manufacturing methods and assure the potency and purity of new pharmaceuticals. HPLC is also used in a variety of other applications, such as analyses of foods and beverages for nutritional labeling and compliance with safety regulations and the testing of water and air purity within the environmental testing industry, as well as applications in other industries, such as chemical and consumer products. HPLC is also used by universities, research institutions and governmental agencies, such as the United States Food and Drug Administration (FDA) and the United States Environmental Protection Agency (EPA) and their foreign counterparts that mandate safety and efficacy testing.

In 2004, Waters introduced a novel technology that the Company describes as ultra performance liquid chromatography that utilizes a packing material with small, uniform diameter particles and a specialized instrument, the ACQUITY UPLC™, to accommodate the increased pressure and narrower chromatographic bands that are generated by these small and tightly packed particles. By using the ACQUITY UPLC, researchers and analysts are able to achieve more comprehensive chemical separations and faster analysis times in comparison with many analyses previously performed by HPLC. In addition, in using the ACQUITY UPLC, researchers have the potential to extend the range of applications beyond that of HPLC, enabling them to uncover more levels of scientific information. While offering significant performance advantages, the ACQUITY UPLC is also compatible with the Company's software products and the general operating protocols of HPLC. For these reasons, the Company's customers and field sales and support organizations are well positioned to utilize this new technology and instrument. In 2018, the Company introduced the ACQUITY™ ARC™ Bio System, a versatile, iron-free, bio-inert, quaternary liquid chromatograph specifically engineered to improve bioseparation analytical methods. The Company also introduced the ACQUITY™ UPLC™ PLUS series in 2018, consisting of the H-Class PLUS, H-Class PLUS Bio and I-Class PLUS systems, which incorporate foundational enhancements into the legacy systems.

Waters manufactures LC instruments that are offered in configurations that allow for varying degrees of automation, from component configured systems for academic teaching and research applications to fully automated systems for regulated and high sample throughput testing, and that have a variety of detection technologies, from optical-based ultra-violet (UV) absorbance, refractive index and fluorescence detectors to a suite of MS-based detectors, optimized for certain analyses.

The primary consumable products for LC are chromatography columns. These columns are packed with separation media used in the LC testing process and are typically replaced at regular intervals. The chromatography column contains one of several types of packing material, typically stationary phase particles made from silica or polymeric resins. As a pressurized sample is introduced to the column inlet and permeates through the packed column, it is separated into its constituent components.

Waters HPLC columns can be used on Waters-branded and competitors' LC systems. The Company believes that it is one of a few suppliers in the world that processes silica and polymeric resins, packs columns and distributes its own products. In doing so, the Company believes it can better ensure product consistency, a key attribute for its customers in quality control laboratories, and can react quickly to new customer requirements. The Company believes that its ACQUITY UPLC lines of columns are used primarily on its

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ACQUITY UPLC instrument systems and, furthermore, that its ACQUITY UPLC instruments primarily use ACQUITY UPLC columns. In 2016, the Company continued to expand its column chemistry capabilities through the introduction of CORTECS™ C₈, CORTECS™ Phenyl, CORTECS™ T3 and CORTECS™ Shield RP18. In 2018, the Company introduced the BioResolve™ RP mAb Polyphenyl columns, which improve the consistency and reliability of the overly complex separations of monoclonal antibodies and antibody-drug conjugates.

The Company's precision chemistry consumable products also include environmental and nutritional safety testing products, including Certified Reference Materials (CRM s) and Proficiency Testing (PT) products. Laboratories around the world and across multiple industries use these products for quality control and proficiency testing and also purchase product support services required to help with their federal and state mandated accreditation requirements or with quality control over critical pharmaceutical analysis. In 2018, the Company introduced the VICAM™ BPATest™, which provides a sensitive, precise determination of Bisphenol A in as little as ten minutes. VICAM also introduced a user-friendly lateral flow zearalenone strip test, the Zearala-V AQUA™ in 2018.

Mass Spectrometry and Liquid Chromatography-Mass Spectrometry

MS is a powerful analytical technology that is used to identify unknown compounds, to quantify known materials and to elucidate the structural and chemical properties of molecules by measuring the masses of molecules that have been converted into ions.

The Company is a technology and market leader in the development, manufacture, sale and service of MS instruments and components. These instruments are typically integrated and used along with other complementary analytical instruments and systems, such as LC, chemical electrophoresis and gas chromatography. A wide variety of instrumental designs fall within the overall category of MS instrumentation, including devices that incorporate quadrupole, ion trap, time-of-flight (ToF), magnetic sector and ion mobility technologies. Furthermore, these technologies are often used in tandem (MS-MS) to maximize the speed and/or efficacy of certain experiments.

Currently, the Company offers a wide range of MS instrument systems utilizing various combinations of quadrupole, ToF and ion mobility designs. These instrument systems are used in drug discovery and development, as well as for environmental, clinical and nutritional safety testing. The overwhelming majority of mass spectrometers sold by the Company are designed to utilize an LC system and a liquid compatible interface (such as an electrospray ionization source) as the sample introduction device. These products supply a diverse market with a strong emphasis on the pharmaceutical, biomedical, clinical, food and beverage and environmental market segments worldwide.

MS is an increasingly important detection technology for LC. The Company's smaller-sized mass spectrometers, such as the single quadrupole detector (SQD) and the tandem quadrupole detector (TQD), are often referred to as LC detectors and are typically sold as part of an LC system or as an LC system upgrade. Larger quadrupole systems, such as the Xevo™ TQ and Xevo™ TQ-S instruments, are used primarily for experiments performed for late-stage drug development, including clinical trial testing. Quadrupole time-of-flight (Q-ToF™) instruments, such as the Company's SYNAPT™ G2-S, are often used to analyze the role of proteins in disease processes, an application sometimes referred to as proteomics . In 2016, the Company introduced the Xevo™ TQ-XS mass spectrometry system enabled by the newly designed StepWave™ SX ion guide, which features a unique combination of ion optics, detection and ionization technologies resulting in levels of sensitivity not previously seen. The Company also introduced SONAR in 2016, which is a new data acquisition technology for use with the Xevo G2-XS that allows for the quantification and identification of lipids, metabolites and proteins in complex samples in a more efficient manner. In 2018, the Company introduced the DART QDa™ system with LiveID™, a direct-from-sample analytical system that verifies sample authenticity or adulteration, specifically for food applications. The Company also introduced the Xevo™ TQ-GC mass spectrometer in 2018, which allows laboratories to meet and exceed low part-per-billion limits of detection when

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quantifying pesticide residues and other contaminants in food using GC-MS/MS methods set forth by worldwide regulatory agencies/authorities. In addition, the Company introduced the RenataDX™ screening system, a flow-injection tandem mass spectrometry system for rapid high-throughput analysis of extracted dried blood spots and other human biological matrices.

LC and MS are typically embodied within an analytical system tailored for either a dedicated class of analyses or as a general purpose analytical device. An increasing percentage of the Company's customers are purchasing LC and MS components simultaneously and it has become common for LC and MS instrumentation to be used within the same laboratory and operated by the same user. The descriptions of LC and MS above reflect the historical segmentation of these analytical technologies and the historical categorization of their respective practitioners. Increasingly in today's instrument market, this segmentation and categorization is becoming obsolete as a high percentage of instruments used in the laboratory embody both LC and MS technologies as part of a single device. In response to this development and to further promote the high utilization of these hybrid instruments, the Company has organized its Waters operating segment to develop, manufacture, sell and service integrated LC-MS systems.

Based upon reports from independent marketing research firms and publicly-disclosed sales figures from competitors, the Company believes that it is one of the world's largest manufacturers and distributors of LC and LC-MS instrument systems, chromatography columns and other consumables and related services.

The Company has been a developer and supplier of software-based products that interface with the Company's instruments, as well as other suppliers' instruments. The Company's newest software technology, UNIFI™, is a scientific information system that is the culmination of a multi-year effort to substantially bring all of Waters' preexisting, distinct software systems under one operating system. UNIFI joins Waters' suite of informatics products—Empower™ Chromatography Data Software, MassLynx™ Mass Spectrometry Software and NuGenesis™ Scientific Data Management System, each of which is used to support innovations within world-leading institutions. UNIFI is the industry's first comprehensive software that seamlessly integrates UPLC chromatography, mass spectrometry and informatics data workflows. In 2016, the Company announced two reference libraries available within UNIFI, the Metabolic Profiling CCS Library and the RapiFluor-MS™ Glycan GU Scientific Library. The Company also introduced Symphony Data Pipeline software in 2016, which is a client-server application that automates the movement and transformation of large amounts of LC-MS data to speed up analytical workflows and liberate scientists from mundane yet necessary tasks associated with managing data files. In 2018, the Company announced new analysis capabilities across a variety of molecules by integrating UNIFI acquired data from the Company's Vion™ IMS QToF™ or Xevo GS XS mass spectrometers with Molecular Discovery's Mass-MetaSite and WebMetabase processing software.

Waters Service

Services provided by Waters enable customers to maximize technology productivity, support customer compliance activities and provide transparency into enterprise resource management efficiencies. The customer benefits from improved budget control, data-driven technology adoption and accelerated workflow at a site or on a global perspective. The Company considers its service offerings to be highly differentiated from our competition, as evidenced by a consistent increase in annual service revenues. The Company's principal competitors in the service market include PerkinElmer, Inc., Agilent Technologies, Inc., Thermo Fisher Scientific Inc. and General Electric Company. These competitors can provide certain services on Waters instruments to varying degrees and always present competitive risk.

The servicing and support of instruments, software and accessories is an important source of revenue and represents over 30% of sales for Waters. These revenues are derived primarily through the sale of support plans, demand services, spare parts, customer performance validation services and customer training. Support plans typically involve scheduled instrument maintenance and an agreement to promptly repair a non-functioning instrument in return for a fee described in a contract that is priced according to the configuration of the instrument.

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TA Products and Markets

Thermal Analysis, Rheometry and Calorimetry

Thermal analysis measures the physical or thermodynamic characteristics of materials as a function of temperature. Changes in temperature affect several characteristics of materials, such as their heat flow characteristics, physical state, weight, dimension and mechanical and electrical properties, which may be measured by one or more thermal analysis techniques, including calorimetry. Consequently, thermal analysis techniques are widely used in the development, production and characterization of materials in various industries, such as plastics, chemicals, automobiles, pharmaceuticals and electronics.

Rheometry instruments often complement thermal analyzers in characterizing materials. Rheometry characterizes the flow properties of materials and measures their viscosity, elasticity and deformation under different types of loading or other conditions. The information obtained under such conditions provides insight into a material's behavior during processing, packaging, transport, usage and storage.

Thermal analysis, rheometry and calorimetry instruments are heavily used in material testing laboratories and, in many cases, provide information useful in predicting the suitability and stability of industrial polymers, fine chemicals, pharmaceuticals, water, metals and viscous liquids in various industrial, consumer goods and healthcare products, as well as for life science research. As with systems offered by Waters, a range of instrument configurations is available with increasing levels of sample handling and information processing automation. In addition, systems and accompanying software packages can be tailored for specific applications.

In 2016, TA introduced a new line of differential scanning calorimeters and thermogravimetric analyzers. These new Discovery DSC systems feature enhanced sensing technologies resulting in unprecedented performance in baseline flatness, sensitivity, resolution and reproducibility. In addition, TA introduced the ACS-2 Air Chiller System, ElectroForce 3310 test instrument and DuraPulse™ Stent Graft test instrument in 2016.

In 2017, TA introduced the TAM Air microcalorimeter. Although designed to characterize the curing of cement, this instrument is an ideal platform for imaginative experimental design in a wide range of applications, including cement and concrete, material science, food, pharmaceuticals and environmental analysis. TA also introduced three new dilatometer product lines in its 800 platform, which are high precision systems designed to measure dimensional changes of a specimen brought about by dynamic thermal events in a wide range of applications, including material science, ceramics and metals. In 2017, TA introduced the Discovery SDT 650, which provides a true simultaneous measurement of weight change and differential heat flow using advanced technologies, such as dual sample TGA, modulated DSC and modulated and hi-resolution TGA. In addition, TA introduced the Discovery HP-TGA750, a benchtop high pressure TGA that utilizes a patented ultra-high resolution magnetic suspension balance and new high precision temperature control system. Late in 2017, TA introduced the Discovery DMA 850, which measures the viscoelastic mechanical properties of material under controlled conditions of temperature, environment and mechanical stimulus (stress or strain). The DMA 850 features frictionless air bearing supports and a linear optical encoder, which ensures stable, accurate, high-resolution displacement measurement across the full travel range and enables displacement control of 5 nm. In 2017, TA introduced the WinTest™ 8.0 software package, which will be standard on all new ElectroForce™ products. In addition, TA introduced the ElectroForce DMA 3200 in 2017, which combines fatigue and dynamic mechanical analysis into a single mechanical test platform.

In September 2016, the Company acquired all of the outstanding stock of Rubotherm GmbH (Rubotherm), a manufacturer of gravimetric analysis systems, for approximately \$6 million in cash, \$5 million of which was paid at closing and an additional \$1 million paid after closing to settle certain liabilities. Rubotherm develops and manufactures analytical test instruments for thermogravimetric and sorption measurements that are used in both industrial and academic research laboratories in disciplines that include chemistry, material science and engineering. The Rubotherm acquisition has helped support and further expand product offerings within TA's thermal analysis business.

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TA Service

Similar to Waters, the servicing and support of TA's instruments is an important source of revenue and represents more than 25% of sales for TA. TA operates independently from the Waters operating segment, though many of its overseas offices are situated in Waters' facilities to achieve operational efficiencies. TA has dedicated field sales and service operations. Service sales are primarily derived from the sale of support plans, replacement parts and billed labor fees associated with the repair, maintenance and upgrade of installed systems.

Global Customers

The Company typically has a broad and diversified customer base that includes pharmaceutical accounts, other industrial accounts, universities and governmental agencies. Purchase of the Company's instrument systems is often dependent on its customers' capital spending, or funding as in the cases of governmental, academic and research institutions, which often fluctuate from year to year. The pharmaceutical segment represents the Company's largest sector and includes multinational pharmaceutical companies, generic drug manufacturers, contract research organizations (CROs) and biotechnology companies. The Company's other industrial customers include chemical manufacturers, polymer manufacturers, food and beverage companies and environmental testing laboratories. The Company also sells to universities and governmental agencies worldwide. The Company's technical sales and support staff members work closely with its customers in developing and implementing applications that meet their full range of analytical requirements. During 2018, 56% of the Company's net sales were to pharmaceutical accounts, 31% to other industrial accounts and 13% to governmental agencies and academic institutions.

The Company typically experiences an increase in sales in the fourth quarter, as a result of purchasing habits for capital goods of many customers who tend to exhaust their spending budgets by calendar year end. The Company does not rely on any single customer for a material portion of its sales. During fiscal years 2018, 2017 and 2016, no single customer accounted for more than 2% of the Company's net sales.

Sales and Service

The Company has one of the largest direct sales and service organizations focused exclusively on the analytical workflows offered by the Company. Across these product technologies, using respective specialized sales and service workforces, the Company serves its customer base with 87 sales offices throughout the world as of December 31, 2018 and approximately 3,900, 3,800 and 3,600 field representatives in 2018, 2017 and 2016, respectively. This investment in sales and service personnel serves to maintain and expand the Company's installed base of instruments. The Company's sales representatives have direct responsibility for account relationships, while service representatives work in the field to install instruments, train customers and minimize instrument downtime. In-house and field-based technical support representatives work directly with customers, providing them assistance with applications and procedures on Company products. The Company provides customers with comprehensive information through various corporate and regional internet websites and product literature, and also makes consumable products available through electronic ordering facilities and a dedicated catalog.

Manufacturing and Distribution

The Company provides high product quality by overseeing each stage of the production of its instruments, columns and chemical reagents.

The Company currently assembles a portion of its LC instruments at its facility in Milford, Massachusetts, where it performs machining, assembly and testing. The Milford facility maintains quality management and environmental management systems in accordance with the requirements of ISO 9001:2015, ISO 13485:2016 and ISO 14001:2015, and adheres to applicable regulatory requirements (including the FDA Quality System

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Regulation and the European In-Vitro Diagnostic Directive). The Company outsources manufacturing of certain electronic components, such as computers, monitors and circuit boards, to outside vendors that meet the Company's quality requirements. In addition, the Company outsources the manufacturing of certain LC instrument systems and components to well-established contract manufacturing firms in Singapore. The Company's Singapore entity is ISO 9001:2015 certified and manages all Asian outsourced manufacturing as well as the distribution of all products from Asia. The Company may pursue outsourcing opportunities as they arise but believes it maintains adequate supply chain and manufacturing capabilities in the event of disruption or natural disasters.

The Company manufactures specialty Supercritical Fluid Chromatography (SFC) and Supercritical Fluid Extraction (SFE) products in its facility in Sharpsburg, Pennsylvania. The Sharpsburg facility is aligned with the policies and procedures for product manufacturing and distribution as adhered to in the Milford, Massachusetts facility and is under the same structural leadership organization.

The Company primarily manufactures and distributes its LC columns at its facilities in Taunton, Massachusetts and Wexford, Ireland. In February 2018, the Company's Board of Directors approved expanding its Taunton location and anticipates spending an estimated \$215 million to build and equip this new state-of-the-art manufacturing facility. The Company has spent \$11 million on this facility through the end of 2018. The Taunton facility processes, sizes and treats silica and polymeric media that are packed into columns, solid phase extraction cartridges and bulk shipping containers in both Taunton and Wexford. The Wexford facility also manufactures and distributes certain data, instruments and software components for the Company's LC, MS and TA product lines. The Company's Taunton facility is certified to ISO 9001:2015. The Wexford facility is certified to ISO 9001:2015 and ISO 13485:2016/EN ISO 13485:2016. VICAM™ manufactures antibody-linked resins and magnetic beads that are packed into columns and kits in Milford, Massachusetts and Nixa, Missouri. The Company manufactures and distributes its Analytical Standards and Reagents and Environmental Resource Associates (ERA) product lines at its facility in Golden, Colorado, which is certified to ISO 9001:2015 and accredited to ISO/IEC 17025:2017, ISO/IEC 17034:16 and ISO Guide 34. Some ERA products are also manufactured in the Wexford, Ireland facility, which is also accredited to ISO/IEC 17025:2005, ISO/IEC 17034:2016.

The Company manufactures and distributes its MS products at its facilities in Wilmslow, England and Wexford, Ireland. Certain components or modules of the Company's MS instruments are manufactured at its facility in Solihull, England and by long-standing outside contractors. Each stage of this supply chain is closely monitored by the Company to maintain high quality and performance standards. The instruments, components or modules are then returned to the Company's facilities, where its engineers perform final assembly, calibrations to customer specifications and quality control procedures. The Company's MS facilities are certified to ISO 9001:2015 and ISO 13485:2016/EN ISO 13485:2016 and adhere to applicable regulatory requirements (including the FDA Quality System Regulation and the European In-Vitro Diagnostic Directive).

TA's thermal analysis, rheometry and calorimetry products are manufactured and distributed at the Company's New Castle, Delaware, Wakefield, Massachusetts, Eden Prairie, Minnesota, Lindon, Utah and Huellhorst, Germany facilities. Similar to MS, elements of TA's products are manufactured by outside contractors and are then returned to the Company's facilities for final assembly, calibration and quality control. The Company's New Castle facility is certified to ISO 9001:2015 and ISO 17025:2005 standards and the Eden Prairie facility is certified to both ISO 9001:2015 and ISO/IEC 17025:2017 standards.

Raw Materials

The Company purchases a variety of raw materials, primarily consisting of high temperature alloy sheet metal and castings, forgings, pre-plated metals and electrical components from various vendors. The materials used by the Company's operations are generally available from a number of sources and in sufficient quantities to meet current requirements subject to normal lead times.

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The Company is subject to rules of the Securities and Exchange Commission (SEC) under the Dodd-Frank Wall Street Reform and Consumer Protection Act, requiring disclosure as to whether certain materials (tantalum, tin, gold and tungsten), known as conflict minerals, which may be contained in the Company's products, are mined from the Democratic Republic of the Congo and adjoining countries. In 2017, the Company was not able to determine with certainty the country of origin of some of the conflict minerals in its manufactured products. However, the Company does not have knowledge that any of its conflict minerals originated from the Democratic Republic of the Congo or adjoining countries. The Company is in the process of evaluating its 2018 supply chain, and the Company plans to file its 2018 Form SD with the SEC in May 2019. The results of this and future evaluations may impose additional costs and may introduce new risks related to the Company's ability to verify the origin of any conflict minerals contained in its products.

In addition, the Company continues to monitor environmental health and safety regulations in countries in which it operates throughout the world, in particular, European Union and China Restrictions on the use of certain Hazardous Substances in electrical and electronic equipment (RoHS) and European Union Waste Electrical and Electronic Equipment directives. Further information regarding these regulations is available on the Company's website, www.waters.com, under the caption "About Waters / Environmental Health & Safety".

Research and Development

The Company maintains an active research and development program focused on the development and commercialization of products that extend, complement and update its existing product offering. The Company's research and development expenditures for 2018, 2017 and 2016 were \$143 million, \$133 million and \$125 million, respectively. In addition, in 2017, the Company incurred a \$5 million charge for acquired in-process research and development related to milestone payments associated with a licensing arrangement for certain intellectual property relating to mass spectrometry technologies yet to be commercialized and for which there was no future alternative use as of the acquisition date. This licensing arrangement is significantly related to new, biologically-focused applications, as well as other applications, and require the Company to make additional future payments of up to \$7 million if certain milestones are achieved, as well as royalties on future net sales.

Nearly all of the Company's LC products have been developed at the Company's main research and development center located in Milford, Massachusetts, with input and feedback from the Company's extensive field organizations and customers. The majority of the Company's MS products are developed at facilities in England and most of the Company's current materials characterization products are developed at the Company's research and development center in New Castle, Delaware. At December 31, 2018, 2017 and 2016, there were 1,011, 1,004 and 971 employees, respectively, involved in the Company's research and development efforts. The Company has increased research and development expenses from its continued commitment to invest significantly in new product development and existing product enhancements, and as a result of acquisitions. Despite the Company's active research and development programs, there can be no assurance that the Company's product development and commercialization efforts will be successful or that the products developed by the Company will be accepted by the marketplace.

Employees

The Company employed approximately 7,200 employees at both December 31, 2018 and 2017 and 6,900 at December 31, 2016, with approximately 39% of the Company's employees located in the United States. The Company believes its employee relations are generally good. The Company's employees are not unionized or affiliated with any internal or external labor organizations. The Company firmly believes that its future success largely depends upon its continued ability to attract and retain highly skilled employees.

Competition

The analytical instrument systems, supplies and services market is highly competitive. The Company encounters competition from several worldwide suppliers and other companies in both domestic and foreign markets for

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each of its three primary technologies. The Company competes in its markets primarily on the basis of product performance, reliability, service and, to a lesser extent, price. Competitors continuously introduce new products and have instrument businesses that are generally more diversified than the Company's business. Some competitors have greater financial resources and broader distribution than the Company's.

In the markets served by Waters, the Company's principal competitors include: Agilent Technologies, Inc., Shimadzu Corporation, Bruker Corporation, Danaher Corporation and Thermo Fisher Scientific Inc. In the markets served by TA, the Company's principal competitors include: PerkinElmer, Inc., Mettler-Toledo International Inc., NETZSCH-Geraetebau GmbH, Thermo Fisher Scientific Inc., Malvern PANalytical Ltd., a subsidiary of Spectris plc and Anton-Paar GmbH.

The market for consumable LC products, including separation columns, is highly competitive and generally more fragmented than the analytical instruments market. The Company encounters competition in the consumable columns market from chemical companies that produce column sorbents and small specialized companies that primarily pack purchased sorbents into columns and subsequently package and distribute columns. The Company believes that it is one of the few suppliers that processes silica and polymeric resins, packs columns and distributes its own products. The Company competes in this market on the basis of performance, reproducibility, reputation and, to a lesser extent, price. In recent years, the Company's principal competitors for consumable products have included: Danaher Corporation; Merck KGaA; Agilent Technologies, Inc.; General Electric Company and Thermo Fisher Scientific Inc. The ACQUITY UPLC instrument is designed to offer a predictable level of performance when used with ACQUITY UPLC columns and the Company believes that the expansion of the ACQUITY UPLC instrument base will enhance its chromatographic column business because of the high level of synergy between ACQUITY UPLC columns and the ACQUITY UPLC instruments.

Patents, Trademarks and Licenses

The Company owns a number of United States and foreign patents and has patent applications pending in the United States and abroad. Certain technology and software has been acquired or is licensed from third parties. The Company also owns a number of trademarks. The Company's patents, trademarks and licenses are viewed as valuable assets to its operations. However, the Company believes that no one patent or group of patents, trademark or license is, in and of itself, essential to the Company such that its loss would materially affect the Company's business as a whole.

Environmental Matters and Climate Change

The Company is subject to foreign and U.S. federal, state and local laws, regulations and ordinances that (i) govern activities or operations that may have adverse environmental effects, such as discharges to air and water as well as handling and disposal practices for solid and hazardous wastes, and (ii) impose liability for the costs of cleaning up and certain damages resulting from sites of past spills, disposals or other releases of hazardous substances. The Company believes that it currently conducts its operations and has operated its business in the past in substantial compliance with applicable environmental laws. From time to time, Company operations have resulted or may result in noncompliance with environmental laws or liability for cleanup pursuant to environmental laws. The Company does not currently anticipate any material adverse effect on its operations, financial condition or competitive position as a result of its efforts to comply with environmental laws.

The Company is sensitive to the growing global debate with respect to climate change. An internal sustainability working group develops increasingly robust data with respect to the Company's utilization of carbon producing substances in an effort to continuously reduce the Company's carbon footprint. In 2018, the Company published a sustainability report identifying the various actions and behaviors the Company has adopted from 2014 to 2017 concerning its commitment to both the environment and the broader topic of social responsibility. See Item 1A, Risk Factors *The effects of climate change could harm the Company's business,*

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for more information on the potential significance of climate change legislation. See also Note 17 in the Notes to the Consolidated Financial Statements for financial information about geographic areas.

Available Information

The Company files or furnishes all required reports with the SEC. The Company is an electronic filer and the SEC maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The address of the SEC electronic filing website is <http://www.sec.gov>. The Company also makes available, free of charge on its website, its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The website address for Waters Corporation is <http://www.waters.com> and SEC filings can be found under the caption Investors .

Forward-Looking Statements

Certain of the statements in this Form 10-K and the documents incorporated herein, may contain forward-looking statements with respect to future results and events, including any statements regarding, among other items, anticipated trends or growth in the Company's business, including, but not limited to, the impact of new or proposed tariff or trade regulations; the impact of foreign currency translation on financial results; development of products by acquired businesses; the growth rate of sales and research and development expenses; the impact of costs associated with developing new technologies and bringing these new technologies to market; the impact of new product launches and the associated costs, such as the amortization expense related to software platforms; geographic sales mix of business; development of products by acquired businesses and the amount of contingent payments to the sellers of an acquired business; anticipated expenses, including interest expense, capitalized software costs and effective tax rates; the impact of the Tax Cuts and Jobs Act (the 2017 Tax Act) in the U.S.; the impact and outcome of the Company's various ongoing tax audit examinations; the achievement of contractual milestones to preserve foreign tax rates; the impact and outcome of litigation matters; the impact of the loss of intellectual property protection; the impact of new accounting standards and pronouncements; the adequacy of the Company's supply chain and manufacturing capabilities and facilities; the impact of regulatory compliance; the Company's expected cash flow, borrowing capacity, debt repayment and refinancing; the Company's ability to fund working capital, capital expenditures, service debt, repay outstanding lines of credit, make authorized share repurchases, fund potential acquisitions and pay any adverse litigation or tax audit liabilities, particularly in the U.S.; future impairment charges; the Company's contributions to defined benefit plans; the Company's expectations regarding changes to its financial position; compliance with applicable environmental laws; and the impact of recent acquisitions on sales and earnings.

Many of these statements appear, in particular, in Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations of this Form 10-K. Statements that are not statements of historical fact may be deemed forward-looking statements. You can identify these forward-looking statements by the use of the words feels , believes , anticipates , plans , expects , may , will , would , intends , estimates , projects , should and similar expressions, whether in the negative or affirmative. These statements are subject to various risks and uncertainties, many of which are outside the control of the Company, including, and without limitation:

Foreign currency exchange rate fluctuations that could adversely affect translation of the Company's future sales, financial operating results and the condition of its non-U.S. operations, especially when a currency weakens against the U.S. dollar.

Current global economic, sovereign and political conditions and uncertainties, particularly regarding the effect of new or proposed tariff or trade regulations; the U.K. voting to exit the European Union as well as the Chinese government's ongoing tightening of restrictions on procurement by government-funded customers; the Company's ability to access capital and maintain liquidity in volatile market conditions;

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changes in timing and demand for the Company's products among the Company's customers and various market sectors, particularly if they should reduce capital expenditures or are unable to obtain funding, as in the cases of governmental, academic and research institutions; the effect of mergers and acquisitions on customer demand for the Company's products; and the Company's ability to sustain and enhance service.

Negative industry trends; changes in the competitive landscape as a result of changes in ownership, mergers and continued consolidation among the Company's competitors; introduction of competing products by other companies and loss of market share; pressures on prices from customers or resulting from competition; regulatory, economic and competitive obstacles to new product introductions; lack of acceptance of new products; expansion of our business in developing markets; spending by certain end-markets; ability to obtain alternative sources for components and modules; and the possibility that future sales of new products related to acquisitions, which trigger contingent purchase payments, may exceed the Company's expectations.

Increased regulatory burdens as the Company's business evolves, especially with respect to the FDA and EPA, among others, as well as regulatory, environmental and logistical obstacles affecting the distribution of the Company's products, completion of purchase order documentation by our customers and ability of customers to obtain letters of credit or other financing alternatives.

Risks associated with lawsuits, particularly involving claims for infringement of patents and other intellectual property rights.

The impact and costs incurred from changes in accounting principles and practices; the impact and costs of changes in statutory or contractual tax rates in jurisdictions in which the Company operates, specifically as it relates to the 2017 Tax Act in the U.S.; shifts in taxable income among jurisdictions with different effective tax rates; and the outcome of and costs associated with ongoing and future tax audit examinations or changes in respective country legislation affecting the Company's effective rates.

Certain of these and other factors are further described below in Item 1A, Risk Factors, of this Form 10-K. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements, whether because of these factors or for other reasons. All forward-looking statements speak only as of the date of this annual report on Form 10-K and are expressly qualified in their entirety by the cautionary statements included in this report. Except as required by law, the Company does not assume any obligation to update any forward-looking statements.

Item 1A: Risk Factors

The Company is subject to risks and uncertainties, including, but not limited to, the following:

The Company's international operations may be negatively affected by political events, wars or terrorism and regulatory changes, related to either a specific country or a larger region. These potential political, currency and economic disruptions, as well as foreign currency exchange rate fluctuations, could have a material adverse effect on the Company's results of operations or financial condition.

Approximately 72% and 71% of the Company's net sales in 2018 and 2017, respectively, were outside of the United States and were primarily denominated in foreign currencies. In addition, the Company has considerable manufacturing operations in Ireland and the United Kingdom, as well as significant subcontractors located in Singapore. As a result, a significant portion of the Company's sales and operations are subject to certain risks, including adverse developments in the political, regulatory and economic environment, in particular, uncertainty regarding possible changes to foreign and domestic trade policy; the effect of the U.K. voting to exit the European Union as well as the financial difficulties and debt burden experienced by a number of European countries; the instability and potential impact of war or terrorism; the instability and possible dissolution of the Euro as a single currency; sudden movements in a country's foreign exchange rates due to a change in a country's sovereign risk profile or foreign exchange regulatory practices; tariffs and other trade barriers; difficulties in staffing and managing foreign operations; and associated adverse operational, contractual and tax consequences.

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Additionally, the U.S. dollar value of the Company's net sales, cost of sales, operating expenses, interest, taxes and net income varies with foreign currency exchange rate fluctuations. Significant increases or decreases in the value of the U.S. dollar relative to certain foreign currencies, particularly the Euro, Japanese yen and British pound, could have a material adverse effect or benefit on the Company's results of operations or financial condition.

Global economic conditions may decrease demand for the Company's products and harm the Company's financial results.

The Company is a global business that may be adversely affected by changes in global economic conditions. These changes in global economic conditions, both inside and outside the U.S., may affect the demand for the Company's products and services. This may result in a decline in sales in the future, increased rate of order cancellations or delays, increased risk of excess or obsolete inventories, longer sales cycles and potential difficulty in collecting sales proceeds. There can be no assurance regarding demand for the Company's products and services in the future.

The Company's financial results are subject to changes in customer demand, which may decrease for a number of reasons, many beyond the Company's control.

The demand for the Company's products is dependent upon the size of the markets for its LC, LC-MS, thermal analysis, rheometry and calorimetry products; the timing and level of capital spending and expenditures of the Company's customers; changes in governmental regulations, particularly affecting drug, food and drinking water testing; funding available to governmental, academic and research institutions; general economic conditions and the rate of economic growth in the Company's major markets; and competitive considerations. The Company typically experiences an increase in sales in its fourth quarter as a result of purchasing habits for capital goods by customers that tend to exhaust their spending budgets by calendar year end. However, there can be no assurance that the Company will effectively forecast customer demand and appropriately allocated research and development expenditures to products with high growth and high margin prospects. Additionally, there can be no assurance that the Company's results of operations or financial condition will not be adversely impacted by a change in any of the factors listed above or the continuation of uncertain global economic conditions.

Additionally, the analytical instrument market may, from time to time, experience low sales growth. Approximately 56% of the Company's net sales in both 2018 and 2017 were to worldwide pharmaceutical and biotechnology companies, which may be periodically subject to unfavorable market conditions and consolidations. Unfavorable industry conditions could have a material adverse effect on the Company's results of operations or financial condition.

Disruption in worldwide financial markets could adversely impact the Company's access to capital and financial condition.

Financial markets in the U.S., Europe and Asia have experienced times of extreme disruption, including, among other things, sharp increases in the cost of new capital, credit rating downgrades and bailouts, severely diminished capital availability and severely reduced liquidity in money markets. Financial and banking institutions have also experienced disruptions, resulting in large asset write-downs, higher costs of capital, rating downgrades and reduced desire to lend money. There can be no assurance that there will not be future deterioration or prolonged disruption in financial markets or financial institutions. Any future deterioration or prolonged disruption in financial markets or financial institutions in which the Company participates may impair the Company's ability to access its existing cash, utilize its existing syndicated bank credit facility funded by such financial institutions, and impair its ability to access sources of new capital. The cost to the Company of any new capital raised and interest expense would increase if this were to occur.

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Competitors may introduce more effective or less expensive products than the Company's, which could result in decreased sales. The competitive landscape may transform as a result of potential changes in ownership, mergers and continued consolidations among the Company's competitors, which could harm the Company's business.

The analytical instrument market and, in particular, the portion related to the Company's HPLC, UPLC, LC-MS, thermal analysis, rheometry and calorimetry product lines, is highly competitive and subject to rapid changes in technology. The Company encounters competition from several international instrument suppliers and other companies in both domestic and foreign markets. Some competitors have instrument businesses that are generally more diversified than the Company's business, but are typically less focused on the Company's chosen markets. Over the years, some competitors have merged with other competitors for various reasons, including increasing product line offerings, improving market share and reducing costs. There can be no assurance that the Company's competitors will not introduce more effective and less costly products than those of the Company or that the Company will be able to increase its sales and profitability from new product introductions. There can be no assurance that the Company's sales and marketing forces will compete successfully against the Company's competitors in the future.

Strategies for organic growth require developing new technologies and bringing these new technologies to market, which could negatively impact the Company's financial results.

The Company's corporate strategy is fundamentally based on winning through organic innovation and deep application expertise. The Company is in the process of developing new products with recently acquired technologies. The future development of these new products will require a significant amount of spending over the next few years before significant, robust sales will be realized. Furthermore, these new products will be sold into both the non-clinical and clinical markets, and any new products requiring FDA clearance may take longer to bring to market. There can be no assurance given as to the timing of these new product launches and the ultimate realization of sales and profitability in the future.

The Company's software or hardware may contain coding or manufacturing errors that could impact their function, performance and security, and result in other negative consequences.

Despite testing prior to the release and throughout the lifecycle of a product or service, the detection and correction of any errors in released software or hardware can be time consuming and costly. This could delay the development or release of new products or services, or new versions of products or services, create security vulnerabilities in the Company's products or services, and adversely affect market acceptance of products or services. If the Company experiences errors or delays in releasing its software or hardware, or new versions thereof, its sales could be affected and revenues could decline. Errors in software or hardware could expose the Company to product liability, performance and warranty claims as well as harm to brand and reputation, which could impact future sales.

The loss of key members of management and the risks inherent in succession planning could adversely affect the Company's results of operations or financial condition.

The operation of the Company requires managerial and operational expertise. None of the Company's key management employees, with the exception of the Chairman and Chief Executive Officer and the Senior Vice President and Chief Financial Officer, have an employment contract with the Company and there can be no assurance that such individuals will remain with the Company. If, for any reason, other such key personnel do not continue to be active in management, the Company's results of operations or financial condition could be adversely affected.

Disruption of operations at the Company's manufacturing facilities could