ILLUMINA INC
Form 10-K
February 12, 2019
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K
þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 30, 2018
or
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number: 001-35406
Illumina, Inc.
(Exact name of registrant as specified in its charter)

Delaware	33-0804655
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
5200 Illumina Way San Diego, California	92122
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (858) 202-4500
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.01 par value	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes þ No o
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 o No þ
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No o
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. o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer þ	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	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 13a of the Exchange Act. o

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

As of February 8, 2019, there were 147 million shares (excluding 45 million shares held in treasury) of the registrant's common stock outstanding. The aggregate market value of the common stock held by non-affiliates of the registrant as of July 1, 2018 (the last business day of the registrant's most recently completed second fiscal quarter), based on the closing price for the common stock on The NASDAQ Global Select Market on June 29, 2018 (the last trading day before July 1, 2018), was $35.9 billion. This amount excludes an aggregate of approximately 18 million shares of common stock held by officers and directors and each person known by the registrant to own 10% or more of the outstanding common stock. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that the registrant is controlled by or under common control with such person.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the 2019 annual meeting of stockholders are incorporated by reference into Items 10 through 14 of Part III of this Report.

ILLUMINA, INC.
FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 30, 2018
TABLE OF CONTENTS

Special Note Regarding Forward-Looking Statements

This annual report on Form 10-K contains, and our officers and representatives may from time to time make, "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will," or the negative of the similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding:

- our expectations as to our future financial performance, results of operations, or other operational results or metrics;
- our expectations regarding the launch of new products or services;
- the benefits that we expect will result from our business activities and certain transactions we have completed, such as product introductions, increased revenue, decreased expenses, and avoided expenses and expenditures;
- our expectations of the effect on our financial condition of claims, litigation, contingent liabilities, and governmental investigations, proceedings, and regulations;
- our strategies or expectations for product development, market position, financial results, and reserves; and
- other expectations, beliefs, plans, strategies, anticipated developments, and other matters that are not historical facts.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy, and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following:

- challenges inherent in developing, manufacturing, and launching new products and services, including expanding manufacturing operations and reliance on third-party suppliers for critical components;
- the timing and mix of customer orders among our products and services;
- the impact of recently launched or pre-announced products and services on existing products and services;
- our ability to develop and commercialize our instruments and consumables, to deploy new products, services, and applications, and to expand the markets for our technology platforms;
- our ability to manufacture robust instrumentation and consumables;
- our ability to identify and integrate acquired technologies, products, or businesses successfully;
- our expectations and beliefs regarding prospects and growth for the business and its markets;
- our expectations regarding the pending acquisition of Pacific Biosciences of California, Inc.;
- the assumptions underlying our critical accounting policies and estimates;
- our assessments and estimates that determine our effective tax rate;
- our assessments and beliefs regarding the outcome of pending legal proceedings and any liability that we may incur as a result of those proceedings;
- uncertainty, or adverse economic and business conditions, including as a result of slowing or uncertain economic growth in the United States or worldwide; and

- other factors detailed in our filings with the SEC, including the risks, uncertainties, and assumptions described in Item 1A "Risk Factors" below, or in information disclosed in public conference calls, the date and time of which are released beforehand.

Any forward-looking statement made by us in this annual report on Form 10-K is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation, and do not intend, to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, or to review or confirm analysts' expectations, or to provide interim reports or updates on the progress of any current financial quarter, in each case whether as a result of new information, future developments, or otherwise.

Available Information

Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports are available free of charge on our website, www.illumina.com. The information on our website is not incorporated by reference into this report. Such reports are made available as soon as reasonably practicable after filing with, or furnishing to, the SEC. The SEC also maintains an Internet site at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that electronically file with the SEC. Copies of our annual report on Form 10-K will be made available, free of charge, upon written request.

Unless the context requires otherwise, references in this annual report on Form 10-K to "Illumina," the "Company," "we," "us," and "our" refer to Illumina, Inc. and its subsidiaries.

PART I

ITEM 1. Business.

Overview

We are the global leader in sequencing- and array-based solutions for genetic and genomic analysis. Our products and services serve customers in a wide range of markets, enabling the adoption of genomic solutions in research and clinical settings. We were incorporated in California in April 1998 and reincorporated in Delaware in July 2000. Our principal executive offices are located at 5200 Illumina Way, San Diego, California 92122. Our telephone number is (858) 202-4500.

Our customers include leading genomic research centers, academic institutions, government laboratories, and hospitals, as well as pharmaceutical, biotechnology, commercial molecular diagnostic laboratories, and consumer genomics companies.

Our portfolio of integrated sequencing and microarray systems, consumables, and analysis tools is designed to accelerate and simplify genetic analysis. This portfolio addresses the range of genomic complexity, price points, and throughput, enabling customers to select the best solution for their research or clinical application.

We have also enabled, or invested in, early-stage companies that are pursuing promising genomics-related technologies. For example, GRAIL, Inc. (GRAIL), formed in 2016, was created to develop a blood test for early-stage cancer detection; and Helix Holdings I, LLC (Helix) was established in 2015 to enable individuals to explore their genetic information by providing sequencing and services for consumers through third-party partners.

On November 1, 2018, we entered into an Agreement and Plan of Merger to acquire Pacific Biosciences of California, Inc. (PacBio) for an all-cash price of approximately $1.2 billion (or $8.00 per share), subject to applicable regulatory approvals. We believe PacBio’s highly accurate long reads combined with our highly accurate and scalable short reads will provide researchers and clinicians with a more perfect view of the genome, enhancing their ability to make novel discoveries and broaden clinical utility across a range of applications. The transaction is expected to close mid-2019. See note “3. Intangible Assets, Goodwill, and Acquisitions” in Part II, Item 8 of this report for further details regarding this acquisition.

Genetics Primer

The instruction set for all living cells is encoded in deoxyribonucleic acid, or DNA. The complete set of DNA for any organism is referred to as its genome. DNA contains small regions called genes, which comprise a string of nucleotide bases labeled A, C, G, and T, representing adenine, cytosine, guanine, and thymine, respectively. These nucleotide bases occur in a precise order known as the DNA sequence. When a gene is “expressed,” a copy of a portion of its DNA sequence called messenger RNA (mRNA) is used as a template to direct the synthesis of a particular protein. Proteins, in turn, direct all cellular function. The illustration below is a simplified gene expression schematic.
Variations among organisms are due, in large part, to differences in their DNA sequences. Changes can result from insertions, deletions, inversions, translocations, or duplications of nucleotide bases. These changes may result in certain genes becoming overexpressed (excessive protein production), underexpressed (reduced protein production), or silenced altogether, sometimes triggering changes in cellular function. The most common form of variation in humans is called a single nucleotide

Table of Contents

polymorphism (SNP), which is a base change in a single position in a DNA sequence. Another type of variation, copy number variations (CNVs), occur when there are fewer or more copies of certain genes, segments of a gene, or stretches of DNA.

In humans, genetic variation accounts for many of the physical differences we see (e.g., height, hair, eye color, etc.). Genetic variations also can have medical consequences affecting disease susceptibility, including predisposition to complex genetic diseases such as cancer, diabetes, cardiovascular disease, and Alzheimer's disease. They can affect individuals' response to certain drug treatments, causing them to respond well, experience adverse side effects, or not respond at all.

Scientists are studying these variations and their consequences in humans, as well as in a broad range of animals, plants, and microorganisms. Such research takes place in government, university, pharmaceutical, biotechnology, and agrigenomics laboratories around the world, where scientists expand our knowledge of the biological functions essential for life. Beginning at the genetic level, our tools are used to elucidate the relationship between gene sequence and biological processes. Researchers who investigate human and non-human genetic variation to understand the mechanisms of disease are enabling the development of more effective diagnostics and therapeutics. They also provide greater insight into genetic variation in plants (e.g., food and biofuel crops) and animals (e.g., livestock and domestic), enabling improvements in crop yields and animal breeding programs.

By empowering genetic analysis and facilitating a deeper understanding of genetic variation and function, our tools advance disease research, drug development, and the creation of molecular diagnostic tests. We believe that this will trigger a fundamental shift in the practice of medicine and health care, and that the increased emphasis on preventive and predictive molecular medicine will usher in the era of precision health care.

Our Principal Markets

Our organization is structured to target the markets and customers outlined below.

Life Sciences

Historically, our core business has been in the life sciences research market. This includes laboratories associated with universities, research centers, and government institutions, along with biotechnology and pharmaceutical companies. Researchers at these institutions use our products and services for basic and translational research across a spectrum of scientific applications, including targeted, exome, and whole-genome sequencing; genetic variation; gene expression; epigenetics; and metagenomics. Next-generation sequencing (NGS) technologies are being adopted due to their ability to cost-effectively sequence large sample sizes quickly and accurately, generating vast amounts of high-quality data. Both private and public funding drive this research, along with global initiatives to characterize genetic variation.

Our products also serve various applied markets including consumer genomics and agrigenomics. For example, in consumer genomics, our customers use our technologies to provide personalized genetic data and analysis to individual consumers. In agrigenomics, government and corporate researchers use our products and services to explore the genetic and biological basis for productivity and nutritional constitution in crops and livestock. Researchers can identify natural and novel genomic variation and deploy genome-wide marker-based applications to accelerate breeding and production of healthier and higher-yielding crops and livestock.

Clinical Genomics

We are focused on enabling translational and clinical markets through the introduction of best-in-class sequencing technology. Further, we are developing sample-to-answer solutions to catalyze adoption in the clinical setting,

including in reproductive and genetic health and oncology. In reproductive health, our primary focus is driving noninvasive prenatal testing (NIPT) adoption globally through our technology, which identifies fetal chromosomal abnormalities by analyzing cell-free DNA in maternal blood. Our NGS technology is also accelerating rare and undiagnosed disease research to discover the genetic causes of inherited disorders by assessing many genes simultaneously. Using NGS can reduce costs compared to traditional methods of disease diagnosis, which are often expensive and inconclusive while requiring extensive testing.

Cancer is a disease of the genome, and the goal of cancer genomics is to identify genomic changes that transform a normal cell into a cancerous one. Understanding these genomic changes will improve diagnostic accuracy, increase understanding of the prognosis, and enable oncologists to target therapies to individuals. Customers in the translational and clinical oncology markets use our products to perform research that may help identify individuals who are genetically predisposed to cancer and to identify molecular changes in a tumor. We believe that circulating tumor DNA (ctDNA) will become an important clinical tool for managing oncology patients during all stages of tumor progression. Our technology is

Table of Contents

being used to research the implications of ctDNA in treatment determination, treatment monitoring, minimal residual disease, and asymptomatic screening. For example, we have invested in, and partnered with GRAIL, which we formed to develop a blood-based test for early-stage cancer detection that is enabled by our sequencing technology.

Our Principal Products and Technologies

Our unique technology platforms support the scale of experimentation necessary for population-scale studies, genome-wide discovery, target selection, and validation studies (see Figure 1 below). Customers use our products to analyze the genome at all levels of complexity, from targeted panels to whole-genome sequencing. A large and dynamic Illumina user community has published tens of thousands of customer-authored scientific papers using our technologies. Through rapid innovation, we are changing the economics of genetic research, enabling projects that were previously considered impossible, and supporting clinical advances towards precision medicine.

Most of our product sales consist of instruments and consumables, which include reagents, flow cells, and microarrays, based on our proprietary technologies. We also perform various services for our customers. For the fiscal years ended December 30, 2018, December 31, 2017, and January 1, 2017, instrument sales represented 17%, 19%, and 20%, respectively, of total revenue; consumable sales represented 65%, 64%, and 64%, respectively, of total revenue; and services represented 18%, 17%, and 15%, respectively, of total revenue.

Figure 1: Illumina Platform Overview:
Sequencing

DNA sequencing is the process of determining the order of nucleotide bases (A, C, G, or T) in a DNA sample. Our portfolio of sequencing platforms represents a family of systems that we believe set the standard for productivity, cost-effectiveness, and accuracy among NGS technologies. Customers use our platforms to perform whole-genome, de novo, exome and RNA sequencing, and targeted resequencing of specific gene regions and genes.

Whole-genome sequencing determines the complete DNA sequence of an organism. In de novo sequencing, the goal is to sequence and assemble the genome of that sample without using information from prior sequencing of that species. In targeted resequencing, a portion of the sequence of an organism is compared to a standard or reference sequence from previously sequenced samples to identify genetic variation. Understanding the similarities and differences in DNA sequence between and within species helps us understand the function of the structures encoded in the DNA.

Our DNA sequencing technology is based on our proprietary reversible terminator-based sequencing chemistry, referred to as sequencing by synthesis (SBS) biochemistry. SBS tracks the addition of labeled nucleotides as the DNA chain is copied in a massively parallel fashion. Our SBS sequencing technology provides researchers with a broad range of applications and the ability to sequence even large mammalian genomes in a few days rather than weeks or years.

Table of Contents

Our sequencing platforms can generate between 500 megabases (Mb) and 6.0 terabases (Tb) (equivalent to approximately 48 human genomes) of genomic data in a single run, depending on the instrument and application. There are different price points per gigabase (Gb) for each instrument, and for different applications, which range from small-genome, amplicon, and targeted gene-panel sequencing to population-scale whole human genome sequencing. Since we launched our first sequencing system in 2007, our systems have reduced the cost of sequencing by a factor of more than 10,000. In addition, the sequencing time per Gb has dropped by a factor of approximately 12,000.

Our BaseSpace Informatics Suite cloud platform plays a critical role in supporting our sequencing applications. BaseSpace Informatics Suite integrates directly with our sequencing instruments, allowing customers to manage their biological sample and sequencing runs, process and analyze the raw genomic data, and derive meaningful results. It facilitates data sharing, provides data-storage solutions and streamlines analysis through a growing number of applications developed by us and the bioinformatics community.

For the fiscal years ended December 30, 2018, December 31, 2017, and January 1, 2017, total sequencing revenue comprised 83%, 83%, and 84%, respectively, of total revenue.

Arrays

Arrays are used for a broad range of DNA and RNA analysis applications, including SNP genotyping, CNV analysis, gene expression analysis, and methylation analysis, and enable the detection of millions of known genetic markers on a single array. Arrays are the primary technology used in consumer genomics applications.

Our BeadArray technology combines microscopic beads and a substrate in a proprietary manufacturing process to produce arrays that can perform many assays simultaneously. This facilitates large-scale analysis of genetic variation and biological function in a unique, high-throughput, cost-effective, and flexible manner. Using our BeadArray technology, we achieve high-throughput analysis via a high density of test sites per array and the ability to format arrays in various configurations. To serve the needs of multiple markets and market segments, we can vary the size, shape, and format of the substrate into which the beads self-assemble and create specific bead types for different applications. Our iScan System and our NextSeq 550 System can be used to image arrays.

For the fiscal years ended December 30, 2018, December 31, 2017, and January 1, 2017, total array revenue comprised 17%, 17%, and 16%, respectively, of total revenue.

Consumables

We have developed various library preparation and sequencing kits to simplify workflows and accelerate analysis. Our sequencing applications include whole-genome sequencing kits, which sequence entire genomes of any size and complexity, and targeted resequencing kits, which can sequence exomes, specific genes, RNA or other genomic regions of interest. Our sequencing kits maximize the ability of our customers to characterize the target genome accurately and are sold in various configurations, addressing a wide range of applications.

Customers use our array-based genotyping consumables for a wide range of analyses, including diverse species, disease-related mutations, and genetic characteristics associated with cancer. Customers can select from a range of human, animal, and agriculturally relevant genome panels or create their own custom arrays to investigate millions of genetic markers targeting any species.

Our Services

We provide whole-genome sequencing, genotyping, NIPT, and product support services. Human whole-genome sequencing services are provided through our CLIA-certified, CAP-accredited laboratory. Using our services, customers can perform whole-genome sequencing projects and microarray projects (including large-scale genotyping studies and whole-genome association studies). We also provide NIPT services through our partner laboratories that direct samples to us on a test send-out basis in our CLIA-certified, CAP-accredited laboratory. In addition, we also offer support services to customers who have purchased our products.

Table of Contents

Intellectual Property

We have an extensive intellectual property portfolio. As of January 10, 2019, we owned or had exclusive licenses to 709 issued U.S. patents and 529 pending U.S. patent applications, including 45 allowed applications that have not yet issued as patents. Our issued and pending patents cover various aspects of our arrays, assays, oligo synthesis, sequencing technology, instruments, digital microfluidics, software, bioinformatics, and chemical-detection technologies, and have terms that expire between 2019 and 2038. We continue to file new patent applications to protect the full range of our technologies. We have filed or have been granted counterparts for many of these patents and applications in foreign countries.

We protect our trade secrets, know-how, copyrights, and trademarks. Our success depends in part on obtaining patent protection for our products and processes, preserving trade secrets, patents, copyrights and trademarks, operating without infringing the proprietary rights of third parties, and acquiring licenses for technology or products. In addition, we invest in technological innovation, and we seek beneficial licensing opportunities to develop and maintain our competitive position.

We are party to various exclusive and nonexclusive license agreements and other arrangements with third parties that grant us rights to use key aspects of our sequencing and array technologies, assay methods, chemical detection methods, reagent kits, and scanning equipment. Our exclusive licenses expire with the termination of the underlying patents, which will occur between 2019 and 2032. We have additional nonexclusive license agreements with various third parties for other components of our products. In most cases, the agreements remain in effect over the term of the underlying patents, may be terminated at our request without further obligation, and require that we pay customary royalties.

Research and Development

We have historically made substantial investments in research and development. Our research and development efforts prioritize continuous innovation coupled with product evolution.

Research and development expense for the fiscal years ended December 30, 2018, December 31, 2017, and January 1, 2017 were $623 million, $546 million, and $504 million, respectively. We expect research and development expense to increase during 2019 to support business growth and continuing expansion in research and product-development efforts.

Marketing and Distribution

We market and distribute our products directly to customers in North America, Europe, Latin America, and the Asia-Pacific region. In each of these areas, dedicated sales, service, and application-support personnel are expanding and supporting their respective customer bases. In addition, we sell through life-science distributors in certain markets within Europe, the Asia-Pacific region, Latin America, the Middle East, and South Africa. We expect to continue increasing our sales and distribution resources during 2019 and beyond as we launch new products and expand our potential customer base.

Manufacturing

We manufacture sequencing and array platforms and reagent kits. In 2018, we continued to increase our manufacturing capacity to meet customer demand. To address increasing product complexity and volume, we continue to automate manufacturing processes to accelerate throughput and improve quality and yield. We are committed to providing medical devices and related services that consistently meet customer and applicable

regulatory requirements. We adhere to access and safety standards required by federal, state, and local health ordinances, such as standards for the use, handling, and disposal of hazardous substances. Our key manufacturing and distribution facilities operate under a quality management system certified to ISO 13485.

Raw Materials

Our manufacturing operations require a wide variety of raw materials, electronic and mechanical components, chemical and biochemical materials, and other supplies. Multiple commercial sources provide many of our components and supplies, but there are some raw materials and components that we obtain from single-source suppliers. To manage potential risks arising from single-source suppliers, we believe that, if necessary, we could redesign our products using alternative components or for use with alternative reagents or develop an internal supply capability. In addition, while we attempt to keep our inventory at minimal levels, we purchase incremental inventory as circumstances warrant to protect our supply chain. If the capabilities of our suppliers and component manufacturers are limited or stopped, due to disasters, quality, regulatory, or other reasons, it could negatively impact our ability to manufacture our products.

Table of Contents

Competition

Although we believe that our products and services provide significant advantages over products and services currently available from other sources, we expect continued intense competition. Our competitors offer products and services for sequencing, SNP genotyping, gene expression, and molecular diagnostics markets. They include companies such as Agilent Technologies, Inc., BGI, Oxford Nanopore Technologies Limited, QIAGEN N.V., Roche Holding AG., and Thermo Fisher Scientific, Inc., among others. Some of these companies have, or will have, substantially greater financial, technical, research, and other resources than we do, along with larger, more established marketing, sales, distribution, and service organizations. In addition, they may have greater name recognition than we do in the markets we address, and in some cases a larger installed base of systems. We expect new competitors to emerge and the intensity of competition to increase. To compete effectively, we must scale our organization and infrastructure appropriately and demonstrate that our products have superior throughput, cost, and accuracy.

Segment and Geographic Information

We have two reportable segments: Core Illumina and one segment related to the combined activities of our Consolidated VIEs. Our Consolidated VIEs currently include only the operations of Helix, whereas prior to the deconsolidation of GRAIL on February 28, 2017, our Consolidated VIEs included the combined operations of Helix and GRAIL.

We currently sell our products to a number of customers outside the United States, including customers in other areas of North America, Latin America, Europe, and the Asia-Pacific region. Shipments to customers outside the United States totaled $1,554 million, or 47%, of total revenue, during fiscal 2018, compared to $1,241 million, or 45%, and $1,104 million, or 46%, in fiscal 2017 and 2016, respectively. We consider the U.S. dollar to be the functional currency of our international operations due to the primary activities of our foreign subsidiaries. We expect that sales to international customers will continue to be an important and growing source of revenue. See note “1. Organization and Summary of Significant Accounting Policies” in Part II, Item 8 of this report for further information concerning our foreign and domestic operations.

Backlog

Our backlog was approximately $909 million and $935 million as of December 30, 2018 and December 31, 2017, respectively. Generally, our backlog consists of orders believed to be firm as of the balance sheet date. However, we may allow customers to make product substitutions as we launch new products. The timing of shipments depends on several factors, including agreed upon shipping schedules, which may span multiple quarters, and whether the product is catalog or custom. We expect approximately 80% of our backlog as of December 30, 2018, to be shipped within the fiscal year ending December 29, 2019. Although we generally recognize revenue when control of our products and services is transferred
to our customers, some customer contracts might require us to defer revenue recognition beyond the transfer of control.

Environmental Matters

We are committed to the protection of our employees and the environment. Our operations require the use of hazardous materials that subject us to various federal, state, and local environmental and safety laws and regulations. We believe that we are in material compliance with current applicable laws and regulations. However, we could be held liable for damages and fines should contamination of the environment or individual exposures to hazardous substances occur. In addition, we cannot predict how changes in these laws and regulations, or the development of new laws and regulations, will affect our business operations or the cost of compliance.

Government Regulation

As we expand product lines to address the diagnosis of disease, regulation by governmental authorities in the United States and other countries will become an increasingly significant factor in development, testing, production, and marketing. Products that we develop in the molecular diagnostic markets, depending on their intended use, may be regulated as medical devices or in vitro diagnostic products (IVDs) by the FDA and comparable agencies in other countries. In the United States, certain of our products may require FDA clearance following a pre-market notification process, also known as a 510(k) clearance, or premarket approval (PMA) from the FDA. The usually shorter 510(k) clearance process, which we used for the FDA-cleared assays that are run on our FDA-regulated MiSeqDx instrument, generally takes from three to six months after submission, but it can take significantly longer. The longer PMA process, which we used for our FDA-cleared RAS panel that is also run on our MiSeqDx instrument, is typically much more costly and uncertain. It can take from 9 to 18 months after a complete filing, but it can take significantly longer and requires conducting clinical studies that are generally more extensive than those required for 510(k) clearance. All of the products that are currently regulated by the FDA as medical devices and

Table of Contents

IVDs are also subject to the FDA Quality System Regulation (QSR). Obtaining the requisite regulatory approvals, including the FDA quality system inspections that are required for PMA approval, can be expensive and may involve considerable delay.

In the U.S., we cannot be certain which of our planned molecular diagnostic products will be subject to the shorter 510(k) clearance process and, in fact, some of our products will need to go through the PMA process. The regulatory approval process for such products may be significantly delayed, may be significantly more expensive than anticipated, and may conclude without such products being approved by the FDA. Without timely regulatory approval, we will not be able to launch or successfully commercialize such products.

Changes to the current regulatory framework, including the imposition of additional or new regulations, could arise at any time during the development or marketing of our products. This may negatively affect our ability to obtain or maintain FDA or comparable regulatory clearance or approval of our products. In addition, regulatory agencies may introduce new requirements that may change the regulatory requirements for us or our customers, or both.

If our products labeled as “For Research Use Only,” or RUO, are used, or could be used, for the diagnosis of disease, the regulatory requirements related to marketing, selling, and supporting such products could be uncertain. This is true even if such use by our customers occurs without our consent. If the FDA or other regulatory authorities assert that any of our RUO products are subject to regulatory clearance or approval, our business, financial condition, or results of operations could be adversely affected.

Our products sold as medical devices or IVDs in Europe will be regulated under the In Vitro Diagnostics Directive (98/79/EC). A new regulation, the in vitro Diagnostic Medical Devices Regulation (EU) 2017/746, the IVDR, has been released and will become fully enforceable in 2020. These regulations include requirements for both presentation and review of performance data and quality-system requirements.

Certain of our products are currently available through laboratories that are certified under the Clinical Laboratory Improvements Amendments (CLIA) of 1988. These products are commonly called “laboratory developed tests,” or LDTs. For a number of years, the FDA has exercised its regulatory enforcement discretion not to regulate LDTs as medical devices if created and used within a single laboratory. However, the FDA is reexamining this regulatory approach and changes to the agency’s handling of LDTs could impact our business in ways that cannot be predicted at this time. In October 2014, the FDA published two draft guidance documents suggesting an approach for registration and listing of laboratories and assays along with a framework for regulation of LDTs by the FDA based on risk to patients rather than whether the LDTs were made by a conventional manufacturer or a single laboratory. The draft framework guidance includes pre-market review for higher-risk LDTs, including many used to guide treatment decisions, as well as companion diagnostics that have entered the market as LDTs. The FDA has also issued a 2017 discussion paper on LDTs. We cannot predict the nature or extent of the FDA's final guidance or regulation of LDTs, in general, or with respect to our or our customers’ LDTs, in particular.

Certification of CLIA laboratories includes standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, and quality control procedures. CLIA also mandates that, for high complexity labs such as ours, to operate as a lab, we must have an accreditation by an organization recognized by CLIA such as the College of Pathologists (CAP), which we have obtained and must maintain. If we were to lose our CLIA certification or CAP accreditation, our business, financial condition, or results of operations could be adversely affected. In addition, state laboratory licensing and inspection requirements may also apply to our products, which, in some cases, are more stringent than CLIA requi