LUMINEX CORP
Form 10-K
February 26, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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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 31, 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 No. 000-30109

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LUMINEX CORPORATION
(Exact name of registrant as specified in its charter)

DELAWARE	74-2747608
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
12212 TECHNOLOGY BLVD., AUSTIN, TEXAS	78727
(Address of principal executive offices)	(Zip Code)

(512) 219-8020
(Registrant's Telephone Number, Including Area Code)

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Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of exchange on which registered
Common Stock, $0.001 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.
þ 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 þ No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
þ 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).
þ 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 an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	þ	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 Exchange Act).

¨ Yes þ No

Based on the closing sale price of common stock on The Nasdaq Global Select Market on June 30, 2018, the aggregate market value of the voting stock held by non-affiliates of the Registrant was $1,219,631,021 as of such date, which assumes, for purposes of this calculation only, that all shares of common stock beneficially held by officers and directors are shares owned by "affiliates."

There were 44,675,028 shares of the Company's Common Stock, par value $0.001 per share, outstanding on February 25, 2019.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2019 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

LUMINEX CORPORATION

FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2018

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SAFE HARBOR CAUTIONARY STATEMENT

This annual report on Form 10-K contains statements that are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Forward-looking statements provide our current expectations of forecasts of future events. All statements other than statements of current or historical fact contained in this annual report, including statements regarding our future financial position, business strategy, impact of the reimbursement landscape, products including ARIES®, VERIGENE® NxTAG®, Muse®, Guava®, easyCyte™, InCyte™, Amnis®, ImageStream®, FlowSight®and CellStream®, assay sales, consumables sales patterns and bulk purchases, budgets, system sales, anticipated gross margins, liquidity, cash flows, projected costs and expenses, taxes, deferred tax assets, regulatory approvals or the impact of laws or regulations applicable to us, plans and objectives of management for future operations, and impact of prior acquisitions or future acquisitions, integration and the expected benefit of our acquisitions are all forward-looking statements. The words “anticipate,” “believe,” “continue,” “should,” “estimate,” “expect,” “intend,” “may,” “plan,” “projects,” “will” and similar expressions as they relate to us, are intended to identify forward-looking statements. These statements are based on our current plans and actual future activities, and our financial condition and results of operations may be materially different from those set forth in the forward-looking statements as a result of known or unknown risks and uncertainties, including, among other things:

- concentration of our revenue in a limited number of direct customers and strategic partners, some of which may experience decreased demand for their products utilizing or incorporating our technology, budget or finance constraints in the current economic environment, or periodic variability in their purchasing patterns or practices as a result of internal resource planning challenges;
- risks and uncertainties relating to market demand and acceptance of our products and technologies, including ARIES®, MultiCode®, NxTAG®, xMAP®, VERIGENE®, Muse®, Guava®, and Amnis®products;
- our ability to scale manufacturing operations and manage operating expenses, gross margins and inventory levels;
- our ability to obtain and enforce intellectual property protections on our products and technologies;
- the impact on our growth and future results of operations with respect to the loss of the LabCorp women’s health business;
- our ability to successfully launch new products in a timely manner;
- dependence on strategic partners for development, commercialization and distribution of products;
- risks and uncertainties associated with implementing our acquisition strategy, our challenge to identify acquisition targets including our ability to obtain financing on acceptable terms;
- our ability to integrate acquired companies or selected assets, including the Flow Cytometry assets recently acquired from EMD Millipore, into our consolidated business operations, and the ability to fully realize the benefits of our acquisitions;
- timing of and process for regulatory approvals;
- competition and competitive technologies utilized by our competitors;
- fluctuations in quarterly results due to a lengthy and unpredictable sales cycle, fluctuations in bulk purchases of consumables, fluctuations in product mix, and the seasonal nature of some of our assays;

- our ability to comply with applicable laws, regulations, policies and procedures;

- the impact of the ongoing uncertainty in global finance markets and changes in government and government agency funding, including its effects on the capital spending policies of our partners and end users and their ability to finance purchases of our products;

- changes in principal members of our management staff;

- potential shortages, or increases in costs, of components or other disruptions to our manufacturing operations;

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- our increasing dependency on information technology to enable us to improve the effectiveness of our operations and to monitor financial accuracy and efficiency;

- implementation, including any modification, of our strategic operating plans;

- uncertainty regarding the outcome or expense of any litigation brought against or initiated by us;

- risks relating to our foreign operations, including fluctuations in exchange rates, tariffs, customs and other barriers to importing/exporting materials and products in a cost effective and timely manner; difficulties in accounts receivable collections; our ability to monitor and comply with foreign and international laws and treaties; and our ability to comply with changes in international taxation policies;

- budget or finance constraints in the current economic environment, or periodic variability in customer purchasing patterns or practices as a result of material resource planning challenges; and

- reliance on third party distributors for distribution of specific Luminex-developed and manufactured assay products.

Many of these risks, uncertainties and other factors are beyond our control and are difficult to predict. Any or all of our forward-looking statements in this annual report may turn out to be inaccurate. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. New factors could also emerge from time to time that could adversely affect our business. The forward-looking statements herein can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and assumptions, including the risks, uncertainties and assumptions outlined above and described in Item 1A “Risk Factors” below. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this annual report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements. When you consider these forward-looking statements, you should keep in mind these risk factors and other cautionary statements in this annual report including in Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in Item 1A “Risk Factors.”

Our forward-looking statements speak only as of the date made. We undertake no obligation to publicly update or revise forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained in this annual report.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to “Luminex,” the “Company,” “we,” “us” and “our” refer to Luminex Corporation and its subsidiaries.

Luminex®, xMAP®, xTAG®, NxTAG®, Luminex® 100/200™, LuminexSD™, FLEXMAP 3D®, MicroPlex®, MAGPIX®, MagPlex®, SeroMAP™, xPONENT®, LumAvidin®, MultiCode®, SYNCT™, ARIES®, VERIGENE®, SENSIPLEX™, MagPlex-TAG™, and TeXuse®, Guava®, easyCyte™, InCyte™, Amnis®, ImageStream®, FlowSight®, CellStream®, INSPIRE™, IDEAS®, SpeedBead®, easyCheck™, FlowCellect®, ViaCount™, and Guava NexMan® are trademarks of Luminex Corporation or one of its subsidiaries. This report also refers to trademarks, service marks and trade names of other organizations.

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PART I
ITEM 1. BUSINESS

Overview

We develop, manufacture and sell proprietary biological testing technologies and products with applications throughout the life sciences industries, including diagnostics, pharmaceutical and research. These industries depend on a broad range of tests, called assays, to perform diagnostic testing and conduct life science research. We have established a position in several segments of the life sciences industries by developing and delivering products that satisfy a variety of customer needs in specific market segments, including multiplexing, accuracy, precision, sensitivity, specificity, reduction of labor and ability to test for proteins and nucleic acids. These needs are addressed by our proprietary technologies.

Multiplexing, the foundation of our Company, allows the end user in a laboratory to generate multiple laboratory results from a single sample with a single assay. This is important because our end user customers, which include laboratory professionals performing discovery, research and clinical laboratories performing tests on patients as ordered by physicians and other laboratories, have a fundamental need to perform high quality testing as efficiently as possible. Until the availability of multiplexing technology, the laboratory professional had to perform one assay at a time in a sequential manner, and if additional testing was required on a sample, a second assay would be performed to generate the second result, and so on until all the necessary tests were performed.

Our xMAP Technology

Our xMAP technology is an open architecture, multiplexing technology that combines existing biological testing techniques with illumination, advanced digital signal processing, detection and proprietary software. With our technology, discrete assays are performed on the surface of color-coded microspheres. These microspheres are read in a compact analyzer that utilizes lasers or light emitting diodes (LEDs), detectors, charge-coupled device imaging and high-speed digital signal processing to simultaneously identify the assay and measure the individual assay results. The key features of xMAP technology include the following:

- Multi-analyte/multi-format

xMAP technology has been designed to simultaneously perform up to 500 distinct assays in a single tube or well of a microtiter plate using only a small amount of sample. Moreover, unlike most existing technologies that are dedicated to only one type of assay, xMAP can perform multiple types of assays including enzymatic, genetic and immunologic tests on the same instrumentation platform.

- Flexibility/scalability

xMAP technology allows flexibility in customizing test panels. Panels can be modified to include new assays in the same tube by adding additional microsphere sets. It is also scalable, meaning that there is no change in the manufacturing process and only minimal changes to the labor required to produce a small or large number of microsphere-based tests.

- Both protein and nucleic acid applications on a single platform

xMAP technology has an advantage due to its ability to analyze both proteins and nucleic acids. This allows customers to utilize a single platform to evaluate samples across more biological parameters and generate a more complete assessment of these samples. Alternative technologies are typically restricted to either proteins or nucleic

acid, requiring customers to use two or more technologies from other vendors to get the same information.

- High throughput

Our technology can perform up to 500 tests in a single well, permitting up to 96,000 tests to be detected in approximately one hour with only a small amount of sample. Rapid sample analysis permits efficient use for high-throughput applications.

- Ease of use

Most xMAP-based assays are simple to perform. A test sample is added to a solution containing microspheres that have been coated with reagents. The solution is then processed through one of our xMAP systems which incorporate proprietary software to automate data acquisition and analysis in real-time.

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- Cost-effective

By performing multiple assays at one time, xMAP technology is designed to be cost effective for customers compared to competitive techniques such as ELISA or real-time PCR. By analyzing only those assays in which a customer is interested, xMAP is also more cost effective than most competing microarray technologies. In addition, microsphere-based assays are inexpensive compared to other technologies, such as chip based microarrays.

Two types of microspheres, polystyrene microspheres and polystyrene magnetic microspheres, are both fundamental components of the xMAP technology. We purchase and manufacture microspheres and, in a proprietary process, dye them with varying intensities of proprietary dyes to achieve up to 500 distinct colors. The specific dye proportions permit each color-coded microsphere to be readily identified based on its distinctive fluorescent signature. Our customers create assays by attaching different biochemical reactants to each distinctly colored microsphere set. These unique reactants bind, or capture, specific substances present in the test sample. The microsphere sets can then be combined in test panels as required by the user, with a maximum of 500 tests per panel. Customers can order either standard microspheres or magnetic microspheres.

To perform an assay using xMAP technology on our systems, a researcher attaches biomarker detectors such as antibodies or nucleic acid oligos to one or more sets of color-coded microspheres, which are then mixed with a test sample. This mixture is injected into the xMAP analyzer, such as the Luminex 200 instrument, where the microspheres pass single-file in a fluid stream through two laser beams. The first laser excites the internal dyes that are used to identify the color of the microsphere and the test being performed on the surface of the microsphere. The second laser excites a fluorescent dye captured on the surface of the microspheres that is used to detect the result of the assay taking place. Our proprietary optics, digital signal processors and software record the fluorescent signature of each microsphere and compare the results to the known identity of that color-coded microsphere set. The results are analyzed and displayed in real-time with data stored on the computer database for reference, evaluation and analysis.

Our xMAP technology is currently being used within various segments of the life sciences industries, including the fields of drug discovery and development, and for clinical diagnostics, bio-defense, food safety and biomedical research.

We have a full range of instruments using our xMAP Technology: our LUMINEX® 100/200™ Systems offer 100-plex testing; our FLEXMAP 3D® System is our high-throughput, 500-plex testing system; and our MAGPIX® System provides 50-plex testing at a lower cost using imaging rather than flow cytometry. By using our xMAP technology, the end users are able to be more efficient by generating multiple simultaneous results per sample. We believe that this technology may also offer advantages in other industries, such as in food safety, animal health and bio-defense/bio-threat markets. Using the xMAP products Luminex has available today, up to 500 simultaneous analyte results can be determined from a single sample.

Our Amnis/Guava® Technologies

Due to our recent acquisition of EMD Millipore Corporation’s flow cytometry portfolio, which closed on December 31, 2018, we now have both Amnis® and Guava® technologies.The Amnis Systems are a family of imaging flow cytometry products for cell-based analysis. With the proprietary Amnis charge-coupled device detection and time-delayed integration (CCD-TDI) technology, the CellStream® provides fluorescence and small particle sensitivity in a highly customizable flow cytometer. The FlowSight® and ImageStream® Imaging Flow Cytometers combine the speed and sensitivity of flow cytometry with the functional detail and spatial information of microscopy. The Guava portfolio of products, which are versatile, easy-to-use cytometry systems based on microcapillary fluidics technology, include the Muse® Cell Analyzer, a simple, compact, and affordable system for absolute cell counting, viability, and

basic cell health analyses, and the Guava easyCyte™ System, a versatile benchtop platform for additional, multi-dimensional cell health and biological assessments.

The Acquisition expands Luminex's existing offering of flow-based detection systems, which is centered around our innovative xMAP® multiplexing technology, with more than 15,000 xMAP systems sold worldwide. The results of operations for the Acquisition will be included in Luminex's consolidated financial statements beginning January 1, 2019.

Our Non-Automated Technologies

Our xTAG technology consists of several components, including multiplexed polymerase chain reaction (PCR) or target identification primers, DNA Tags, xMAP microspheres and data analysis software. xTAG technology permits the development of molecular diagnostic assays for clinical use by hospital and reference laboratories. xTAG technology has also been applied to human genetic assays, pharmacogenetic assays and infectious disease assays.

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Our MultiCode technology is based upon a unique assay chemistry that is a flexible platform for both real-time PCR and multiplex PCR-based applications. MultiCode-based PCR assays are primarily used for the detection of infectious diseases and genetic-based conditions. We have multiple molecular diagnostic (MDx) assays based on the MultiCode chemistry. MultiCode products are based upon the unique MultiCode bases, isoC and isoG. The synthetic isoC:isoG DNA base pair differs from the naturally occurring base pairs in its hydrogen bonding pattern. As a result, the MultiCode bases, isoC and isoG, can only pair with each other, but can co-exist with naturally occurring nucleotide pairs. This property enables site-specific incorporation of the isobases during amplification. The MultiCode base pair is recognized by naturally occurring enzymes and can be used for the specific placement of reporter molecules and to increase the molecular recognition capabilities of hybridization-based assays. The MultiCode base pair enables solutions to complex molecular challenges that were previously not possible with natural nucleic acid alone.

We have multiple assay development activities ongoing and these activities are focused in the areas of infectious disease, human genetics, and pharmacogenomics.

Our ARIES® Technology

The ARIES® System is our sample to answer platform for our MultiCode®-RTx technology, including In Vitro Diagnostic (IVD) assays. The ARIES® System is a clinical test system which automates and integrates extraction of nucleic acid from a clinical sample, performs real-time PCR, and detects multiple signals generated by target-specific probes. The ARIES® System is used with specific assays to measure multiple analytes indicative of infectious disease. The ARIES® System uses internal barcode scanning and other advanced features to minimize operator errors. Each independent module supports from one to six cassettes, allowing both STAT and batch testing. The ARIES® System can run both IVD and MultiCode® Analyte Specific Reagents (ASRs) simultaneously with a common Universal Assay Protocol.

Our VERIGENE Technology

Our offering in the molecular diagnostic market segment includes proprietary diagnostic tools that enable rapid and accurate detection of respiratory, gastrointestinal and bloodstream infections. Our U.S. Food and Drug Administration (FDA) cleared VERIGENE® Gram-Positive Blood Culture (BC-GP) and Gram-Negative Blood Culture (BC-GN) test panels for the early detection of pathogens associated with bloodstream infections are leading products in the high-growth bloodstream infection testing segment. In addition to detecting bacteria, these panels also detect yeast and identify antibiotic resistance markers. In contrast to traditional methodologies, which can take several days, these assays enable physicians to identify pathogens, including any associated resistance markers, and prescribe the most appropriate antibiotic regimen, all within 2.5 hours after identification of a positive blood culture. The ability for clinicians to make earlier, better informed therapeutic decisions results in improved patient outcomes and lower healthcare costs. Our VERIGENE product offering also includes FDA-cleared products for the detection of gastrointestinal and respiratory infections. These consist of a targeted product for the detection of C. difficile, as well as highly multiplexed molecular enteric, blood and respiratory pathogen panels which test for a wide spectrum of microorganisms often associated with these types of infections. With the combination of the ARIES® and VERIGENE platforms, Luminex offers customers automated molecular platforms for both syndromic and targeted molecular diagnostic testing.

The VERIGENE System is an automated multiplex-capable system that rapidly and accurately detects infectious pathogens and drug resistance markers. The VERIGENE System consists of: (i) VERIGENE Test Cartridges, which are single-use, self-contained test units, and (ii) VERIGENE instrumentation, including the VERIGENE Processor SP, which is a modular bench-top analyzer, that combines automated nucleic acid extraction, purification, amplification (if needed), and hybridization in each module, as well as the VERIGENE Reader, which manages sample information and reads results from processed cartridges. Tests that run on the VERIGENE System are primarily designed to

identify infections in the bloodstream, respiratory tract, and gastrointestinal tract.

The VERIGENE System utilizes advanced automation and proprietary chemistry to enable rapid sample to result detection of nucleic acid and protein targets. NanoGrid Technology, a unique gold nanoparticle probe chemistry, is the driving force behind all VERIGENE tests, providing a foundation for the VERIGENE System's menu of clinically meaningful diagnostics.

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In addition to our menu of infectious disease tests, we are currently developing a next generation VERIGENE System, VERIGENE II, that we expect will deliver an improved user experience. This next generation system is designed to provide a reduced time to result, an improved user interface and a room temperature cartridge, all in a fully automated sample to result system with an optimized footprint. In addition, customers using this system will have the ability to select both individual and groups of targets on assays using Flex pricing. This approach to target selection allows customers to save money by only paying for the targets they wish to see, which will often align with healthcare standard of care guidelines, when available. If these results do not provide a conclusive diagnosis, additional targets that were tested for but not released can immediately be viewed for an incremental charge.

Our Market Approach

We primarily serve the life sciences industries by marketing products, including our specific testing equipment and assays, to various types of testing laboratories. We have a large base of installed systems that has grown primarily from the following:

- Placements made by customers within our Licensed Technologies Group (LTG) in which customers either:
- license our xMAP technology and develop products that incorporate our xMAP technology into products that they then sell to end users, or
- purchase our proprietary xMAP laboratory instrumentation and our proprietary xMAP microspheres and sell xMAP-based assays and/or xMAP-based testing services, which run on the xMAP instrumentation, and pay a royalty to us; and
- A direct sales force that focuses on the sale of molecular diagnostic assays that run on our systems.

As of December 31, 2018, Luminex had 74 strategic partners, of which 50 have released commercialized reagent-based products utilizing our technology. Our remaining partners are in various stages of development and commercialization of products that incorporate our technology. Luminex and these partners have sold approximately 15,979 xMAP-based instruments in laboratories worldwide as of December 31, 2018. Our remaining LTG customers are in various stages of development and commercialization of products incorporating our technology.

A primary focus for our growth is the development and sale of molecular diagnostic assays utilizing our proprietary MultiCode® and VERIGENE technologies for use on our installed base of systems. We utilize a direct sales model for sales of these products, which is intended to take advantage of our increasing installed base of instruments. Our assays are primarily focused on multiplexed applications for the human molecular clinical diagnostics market. Our assays are also currently focused on three segments of the molecular diagnostic testing market: human genetics, personalized medicine and infectious disease.

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The following systems and assays are available on the market as of December 31, 2018:

	FDA		CE-IVD MARK	
	Clearance	Commercial Launch	Declaration	Commercial Launch
ARIES® HSV 1&2 Assay	þ	2015 - Q4	þ	2016 - Q1
ARIES® Flu A/B & RSV Assay	þ	2016 - Q2	þ	2016 - Q2
ARIES® Group B Streptococcus (GBS) Assay	þ	2017 - Q1	þ	2016 - Q4
ARIES® Bordetella Assay	þ	2017 - Q2	þ	2017 - Q3
ARIES® Norovirus Assay			þ	2017 - Q2
ARIES® C. Difficile Assay	þ	2017 - Q3	þ	2017 - Q3
ARIES® Group A Strep Assay	þ	2017 - Q4	þ	2017 - Q4
NxTAG® Respiratory Pathogen Panel (RPP)	þ	2016 - Q1	þ	2015 - Q4
VERIGENE® Clostridium Difficile Test (CDF)	þ	2012 - Q4	þ	2013 - Q2
VERIGENE® Enteric Pathogens Test (EP)	þ	2014 - Q4	þ	2015 - Q4
VERIGENE® Respiratory Pathogens Flex Test (RP Flex)	þ	2015 - Q4	þ	2015 - Q2
VERIGENE® Gram-Negative Blood Culture Test (BC-GN)	þ	2014 - Q2	þ	2013 - Q1
VERIGENE® Gram-Positive Blood Culture Test (BC-GP)	þ	2012 - Q4	þ	2012 - Q1
xTAG® CYP2C19 Kit v3	þ	2013 - Q4	þ	2013 - Q4
xTAG® CYP2D6 Kit v3	þ	2011 - Q2	þ	2013 - Q2
xTAG® Cystic Fibrosis (CFTR) 39 Kit v2	þ	2009 - Q4	þ	2012 - Q1
xTAG® Cystic Fibrosis (CFTR) 60 Kit v2	þ	2010 - Q1		
xTAG® Cystic Fibrosis (CFTR) 71 Kit v2			þ	2009 - Q3
xTAG® Gastrointestinal Pathogen Panel (GPP)	þ	2013 - Q1	þ	2011 - Q2
xTAG® Respiratory Viral Panel (RVP)	þ	2008 - Q1	þ	2007 - Q4
xTAG® Respiratory Viral Panel (RVP) FAST v2			þ	2011 - Q4

We have plans to submit additional assays to regulatory authorities in 2019, including the FDA and foreign equivalents, for market authorization in order to comply with established guidelines across the jurisdictions in which we participate.

Industry Background

The life sciences industries use assays to detect the presence and characteristics of certain biochemicals, proteins or nucleic acids in a sample. Drug discovery, genetic analysis, pharmacogenomics, clinical diagnostics and general biomedical research all use assays. For example, assays can be used to:

- measure the presence and quantity of substances such as infectious agents, antigens for histocompatibility, hormones, cancer markers and other proteins in a patient's blood, other body fluid or tissue to assist physicians in diagnosing, treating or monitoring disease conditions;
- detect genetic variations, such as single nucleotide polymorphisms or genetic mutations present in inherited diseases;
- measure the response to a compound or dosage by measuring cellular activity to assist in drug discovery and development; and

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- assist physicians in prescribing or dosing the appropriate drug therapy based on the patient's genetic makeup, a field known as pharmacogenetics.

The life sciences customer can purchase assays in the form of complete off-the-shelf kits, develop them from scratch or utilize a customized service to meet the customer's specific needs.

The table below briefly describes the key assay technologies in the life sciences industries:

KEY TECHNOLOGIES	DESCRIPTION	MARKETS SERVED
Sequencing	Instruments which "read" the nucleotide sequence of DNA or ribonucleic acid (RNA) by a variety of methods including Next Generation Sequencing methods	Biomedical research and clinical diagnostics
BioChips/Microarrays	High-density arrays of DNA fragments or proteins attached to a flat glass or silicon surface	Biomedical research and clinical diagnostics
Automated Immunoassays	Automated test tube-based instruments used for detecting antibodies, proteins and other analytes	Clinical diagnostics
Gels and blots	Physical separation of molecules or analytes for visualization	Biomedical research and clinical diagnostics
PCR methods	Tests which use PCR technology to test DNA and RNA	Nucleic acid testing in clinical diagnostics and biomedical research
Microfluidics chips	Miniaturized liquid handling system on a chip	Biomedical research and clinical diagnostics
Microtiter-plate based assays	Plastic trays with discrete wells in which different types of assays are performed, usually Enzyme-Linked Immuno-Sorbent Assay (ELISA) tests	Drug discovery, clinical diagnostics and biomedical research
Genotyping technologies	DNA primers or probes designed to identify small differences between DNA targets	Drug discovery, clinical diagnostics and biomedical research
Gene expression technologies	DNA primers or probes designed to measure the degree of transcriptional activity of a specific gene, indicating how active the cells are in making the protein encoded by that gene	Drug discovery, clinical diagnostics and biomedical research
Mass Spectrometry	Analytical technique and type of instrument used to identify the mass of ionized molecules or molecular fragments	Blood culture identification, pathogen fingerprinting

The table below briefly describes our key systems, technologies and our related revenue streams:

SYSTEMS	TECHNOLOGIES
Luminex® 100/200™	xMAP Technology
FLEXMAP® 3D	xMAP Technology
MAGPIX®	xMAP Technology
ARIES® and ARIES® M1	xTAG® and MultiCode Technologies
VERIGENE®	NanoGrid Technology
Amnis® Flowsight®	Amnis CCD-TDI Technology
Amnis® Imagestream®	Amnis CCD-TDI Technology
Amnis® Cellstream®	Amnis CCD-TDI Technology
Guava easyCyte™	Guava Microcapillary Technology
Muse® Cell Analyzer	Guava Microcapillary Technology

Business Strategy

Our Company’s current focus is the transition from a technology-based tools company to a market-based diagnostic company and the establishment of Luminex as a market leader in the molecular diagnostic market. To achieve these objectives, we have implemented and are pursuing the following strategies:

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- Focus on key markets

We have identified the following key market segments: (i) molecular infectious disease, (ii) genetic or inherited disease, (iii) human leukocyte antigen (HLA) transplant diagnostics, (iv) immunodiagnostics and (v) life sciences research. We will continue to employ a combination of a partnership-driven business model and a product-driven business model focused on selected market segments and assay applications.

- Develop and deliver market-leading molecular diagnostic platforms and assays

Our research and development and our acquisition activity has expanded the breadth of technology and solutions we offer our customers to meet their needs. We acquired the MultiCode RTx real-time PCR technology for both quantitative and qualitative low-plex real-time PCR assays and the GenturaDx IDbox sample to answer platform, which is compatible with our MultiCode RTx technology, to provide our customers with a complete system for their real-time PCR assays. The GenturaDx IDbox was further developed and launched as the ARIES® System. A key focus currently is the development of additional assays for our ARIES® System. The ARIES® System, when combined with our proprietary real-time PCR chemistry and a new menu of highly automated assays that we are developing, is designed to offer a differentiated, easy to use diagnostic solution. The ARIES® System is designed to help clinical diagnostic laboratories overcome their daily challenges: minimizing healthcare cost increases while maintaining the overall quality of healthcare, the scarcity of highly trained laboratory personnel and limited lab bench space. The ARIES® System offers barcode-based data entry, an efficient workflow, a slim design that occupies minimal bench space, universal assay protocols that enable true walkaway automation and ability to simplify laboratory developed tests (LDTs).

The VERIGENE System offers automated, cost-effective multiplex capabilities that rapidly and accurately detect infectious pathogens and drug resistance markers, without relying on time-consuming culture methods. We currently offer assays on the VERIGENE platform in the categories of Bloodstream Infection Tests, Gastrointestinal Infection Tests and a Respiratory Infection Test. The VERIGENE Bloodstream Infection Tests provide cost-effective bacterial identifications and antibiotic resistance determinations directly from positive blood culture bottles up to 48 hours faster than conventional methods. The BC-GP test provides 15 different targets, and the BC-GN test provides 14 different targets. VERIGENE enables an earlier shift from empiric to targeted antibiotic treatment and differentiates potential blood culture contaminants. As a result, the VERIGENE System delivers better outcomes, improved patient care, and true antibiotic stewardship, all at a lower cost.

Testing for gastrointestinal pathogens has traditionally been labor-intensive, unpleasant for technologists to perform, has low sensitivity, and can take as long as five to seven days to produce definitive results. The VERIGENE C. difficile Test for healthcare-acquired diarrhea with 027 hypervirulent strain differentiation and VERIGENE Enteric Pathogens Test for community-acquired diarrhea with nine bacterial and viral targets require less than five minutes of user hands-on time and deliver comprehensive results directly from a stool sample in less than two hours. As a result, the VERIGENE System provides earlier optimization for patient treatment and improved laboratory and hospital efficiency.

Influenza is highly contagious and affects up to 20% of the U.S. population each year. It is responsible for more than 200,000 hospitalizations, and as many as 49,000 deaths, each year depending on the severity of the season. Influenza can lead to serious complications such as pneumonia, bronchitis, sinus infections, and a general worsening of chronic conditions. Respiratory pathogens are responsible for more than one billion annual cases of the common cold and other related illnesses. They are recognized as a serious contributor to respiratory ailments in children, the elderly, and the immunocompromised and are commonly mistreated with unnecessary antibiotics due to delays in diagnosis. The VERIGENE Respiratory Pathogens Flex (RP Flex) provides viral identification information clinicians need to

select appropriate treatment for their patients. VERIGENE RP Flex can limit misuse and overuse of antibiotics, which are ineffective and not indicated for viral infections, and it can provide results within two hours.

- Develop next generation products

We have developed a full range of multiplexing instruments and consumables to cover a broad range of customer applications and budgets. We have developed, and continue to improve, our proprietary chemistries for our multiplex assays in areas such as human genetic testing, personalized medicine testing and infectious disease testing. All of these technology solutions provide our customers with a breadth of innovative solutions to meet their many testing needs.

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We have continued the development of the VERIGENE II System. We initiated clinical studies on the system and its first assay in 2018 and currently expect to commercially launch the VERIGENE II System in 2019. We are also developing the next generation Guava System, acquired as part of the Acquisition. We currently believe the Guava Next Gen System will commercially launch by the end of 2019.

In the fourth quarter of 2015, we launched our sample to answer platform, ARIES® System. We also received FDA clearance for a number of assays that run on the ARIES® System as noted on page 5. We have plans to submit additional assays to regulatory authorities in 2019, including the FDA and foreign equivalents, for market authorizations.

In addition, we are collaborating with industry participants, biomedical research institutions and government entities to develop additional products on our platform. We continuously consider other adjacent markets where our platform and assay offerings would be beneficial.

We have improved the simplicity and ease of use of our multiplex products through the development of a version of our multiplex PCR technology. This NxTAG chemistry enables customers to experience streamlined workflow without sacrificing throughput. We recognize that the crucial aspect of our current technology that we want to preserve for our larger customers is the ability to process samples from 1 to 96 patients in a single batch. This throughput flexibility and capacity is a crucial aspect for tests like our xTAG Respiratory Viral Panel (RVP), in which seasonality and local outbreaks can cause testing volumes to surge unpredictably. We offer the convenience of a one-step workflow with the throughput of a batch-based system. In addition, products using this chemistry are expected to have the convenience of room temperature shipping and storage. Additionally, we continue pursuing projects such as the development of consumables, automation, software and the expansion and enhancement of our multiplexing capabilities to advance our technologies and market acceptance.

We are working on the development of a next generation bead-based multiplexing instrument. This new system would provide the opportunity to address both expanding and evolving market needs, plus an opportunity for existing users to upgrade to a refreshed version of bead-based multiplexing. After determining requisite performance criteria, we commenced the development of this new system utilizing third-party resources. We currently expect to have a commercial launch in 2019.

- Actively pursuing acquisitions that could accelerate our business strategies

We utilize analytical tools and an evaluation template to assess potential acquisition targets to accelerate our business strategies in the key markets described above. This approach led to several successful acquisitions historically, including GenturaDx, which is the foundation of our ARIES® System, the acquisition of Nanosphere, which is the foundation of the VERIGENE System and our recent acquisition of EMD Millipore Corporation’s flow cytometry portfolio. We actively evaluate opportunities to enhance our capabilities or our access to targeted markets or technologies, or provide us other advantages in executing our business strategies in our key markets.

- Continue to develop the partnership channel focused in select key markets

As of December 31, 2018, 50 of our 74 strategic partners have developed and commercialized xMAP based assays and are paying royalties to us. We also have strategic partners who distribute Luminex products. During 2018, the 50 strategic partners who have commercialized xMAP based assays accounted for approximately 54% of our total revenue and all of our strategic partners represented approximately 55% of our total revenue. We intend to continue pursuing opportunities to expand market acceptance of xMAP technology through development, marketing and distribution partnerships with leading companies in the life sciences markets. By leveraging our strategic partners’ market positions and utilizing their distribution channels and marketing infrastructure, we believe we can continue to

expand our installed instrument base. Furthermore, our partners' investments in research and development for xMAP applications provide Luminex xMAP customers with more assay options than any one company or Luminex could develop and commercialize individually.

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We continue to focus our commercialization efforts through our strategic partners covering large sectors of the life science research market, where Luminex believes it has competitive advantages over alternative technologies and approaches. We define strategic partners as those companies in the life sciences markets that develop and distribute assays and tests on xMAP technology or may only distribute our xMAP technology based systems and consumables. With our partners' support and through our direct commercial efforts in the molecular diagnostics clinical laboratory segment, we have targeted major pharmaceutical companies, large clinical laboratories, research institutions and major medical institutions for our principal marketing efforts. We believe that these customers provide the greatest opportunity for maximizing the use of xMAP based products and that continued adoption by these industry leaders will promote wider market acceptance of our xMAP technology.

Products

Instruments

Luminex® 100/200™. The Luminex 100/200 Systems are compact analyzers that integrate fluidics, optics and digital signal processing to measure up to 100 analytes simultaneously in a single tube or well of a microtiter plate using only a small amount of sample. By combining lasers with digital signal processors and microcontrollers, these systems perform rapid, multi-analyte profiles under the control of a Windows-based personal computer and our proprietary software.

FLEXMAP 3D®. The FLEXMAP 3D System is intended for use as a general laboratory instrument in the life sciences, diagnostics, and associated markets. This device can simultaneously measure up to 500 analytes from a single sample and offers increased speed and enhanced ease-of-use and serviceability. Like our Luminex 100/200 Systems, the FLEXMAP 3D System combines lasers with digital signal processors and microcontrollers and these systems perform rapid, multi-analyte profiles under the control of a Windows-based personal computer and our proprietary software.

MAGPIX®. The MAGPIX System is a versatile multiplexing analyzer capable of performing qualitative and quantitative analyses of proteins and nucleic acids in a variety of sample matrices. This system can measure up to 50 analytes in a single reaction volume, reducing sample input, reagents and labor, while simultaneously improving productivity. The MAGPIX System is based on an innovative detection mechanism that uses LEDs and a charge-coupled device (CCD) imaging system, rather than the lasers and detection mechanisms used in our flow cytometry-based instruments.

ARIES®. The ARIES® System is a sample to answer real-time PCR platform. The ARIES® System uses internal barcode scanning and other advanced features to minimize operator errors. Two independent modules each support from one to six cassettes, allowing for both STAT and batch testing. The ARIES® System can run both IVD assays and MultiCode® ASRs simultaneously with a common Universal Assay Protocol. An integrated touchscreen computer eliminates the need for a separate computer, stand-alone keyboard and mouse, thus maximizing valuable bench space.

ARIES® M1. The ARIES® M1 System is a single-module version of the ARIES® System. It shares the same cassette-based sample to answer molecular diagnostic workflow as the ARIES® System, reducing hands-on time and simplifying operations. The ARIES® System is also able to run up to 6 different assays in different sample types in a random batch via Universal Assay Protocol, including laboratory developed tests (LDT).

VERIGENE®. The VERIGENE System is a semi-automated, multiplex, molecular analysis system for the clinical diagnostics market. The VERIGENE System consists of a microfluidics processor, touchscreen reader and disposable test cartridges. The microfluidics processor interacts with and manipulates various functional components of the test cartridge, accomplishing a number of necessary steps, including target binding to the nucleic acid, gold nanoparticle

probe hybridization, intermediate washes, and signal amplification. The reader houses the optical detection module that illuminates the test slide and automated spot recognition software analyzes the resulting signal intensities and provides the test results. The reader also serves as the control station for the VERIGENE System and features a simple and intuitive touchscreen interface that allows users to track samples and test cartridges, initiate and monitor test processing, analyze results and generate reports. The reader is web-enabled to allow remote access to results and reports.

Amnis® Flowsight® Imaging Flow Cytometer. The Flowsight Imaging Flow cytometer provides high-sensitivity flow cytometry and imagery with up to twelve 20x multi-color images of every cell, including side scatter and brightfield, at up to 5,000 events per second. It is upgradeable to 4 lasers, offers automated sample loading for walk-away operations and is supported with image analysis software with fluorescence compensation and analysis wizards.

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Amnis® Imagestream® Mark II Imaging Flow Cytometer. The Imagestream System is a benchtop, multispectral, imaging flow cytometer designed for the acquisition of up to 12 channels of cellular imagery at up to 60X magnification. By collecting large numbers of digital images per sample and providing a numerical representation of image-based features, the ImageStream System combines the per cell information content provided by standard microscopy with the statistical significance afforded by large sample sizes common to standard flow cytometry. With the ImageStream System, fluorescence intensity measurements are acquired as with a conventional flow cytometer; however, the best applications for the ImageStream System take advantage of the system's imaging abilities to locate and quantify the distribution of signals on in or between cells.

Amnis® Cellstream®. The new CellStream Flow Cytometer delivers high sensitivity and flexibility for cell and particle analysis. This compact system contains patented CCD-TDI technology unique to our Amnis Flow Cytometers and may be configured with up to seven lasers to adapt to a wide range of analytical requirements. With highly sensitive and configurable optics, researchers benefit from multiparameter detection capabilities, while maintaining the flexibility to tailor and expand the system according to their research needs and budget.

Guava easyCyte™ Benchtop Flow Cytometer. The Guava easyCyte line includes compact benchtop flow cytometers models that offer up to 3 lasers and 14 parameters with excellent sensitivity and optional high throughput auto-sampling capabilities. Guava easyCyte systems use patented, microcapillary, laser-based technology capable of detecting mammalian and microbial cells, particles, and beads. A sample of fluorescently labeled cells is aspirated into a uniquely proportioned microcapillary flow cell providing direct absolute counting of cells without reference beads. Forward and side scatter characteristics are detected by photodiode, and fluorophores excited by the violet, blue, or red laser emit signals that are spectrally filtered to resolve up to 10 fluorophores simultaneously. The instruments are supported by a line of 40 reagent FlowCellect® Kits and elegant InCyte™ acquisition and analysis software.

Muse®Cell Analyzer. The Muse Cell Analyzer is a simple, compact, easy-to-use benchtop device that uses patent-pending, miniaturized fluorescent detection and microcapillary technology to deliver accurate, precise and quantitative cell analysis. It is versatile enough to analyze both suspension and adherent cells 2–60 μm in diameter and includes a user-friendly touchscreen interface, intuitive software and optimized "Mix-and-Read"assays.

Consumables

MicroPlex® Microspheres. Our Luminex 100/200, FLEXMAP 3D and MAGPIX Systems use polystyrene microspheres that are approximately 5.6 microns in diameter. We dye the microspheres in sets with varying intensities of a red and a near infrared dye to achieve up to 100 distinct color sets. Each microsphere can be coupled with proteins, nucleic acids or other molecules to enable biological assays.

MagPlex® Microspheres. These microspheres feature super-paramagnetic properties that make them ideal for running automated xMAP®-based assays. We dye the microspheres in sets with varying intensities of a red and a near infrared dye to achieve up to 500 distinct color sets. These microspheres can be moved or held in place by a magnetic field. Many automated systems utilize magnetic properties to automate the performance of the assay. Automating sample testing using MagPlex microspheres on a robotic sample preparation system decreases hands-on technician time, improves precision and streamlines workflow.

xTAG® Microspheres. These dyed microspheres are linked to a set of 100 proprietary nucleic acid capture sequences providing a "universal array" for DNA and RNA work. They are designed for conducting genotyping and other nucleic acid-based experiments in the life sciences, pharmaceutical and clinical diagnostic markets. When used in conjunction with our Luminex systems, xTAG microspheres are designed to simplify the molecular assay development process and increase assay flexibility. xTAG microspheres may be used by customers to develop LDT assays and are used in Luminex's xTAG assay kits.

SeroMAP™ Microspheres. These 100 distinct sets of microspheres are designed for specific protein-based serological applications. Certain Luminex partners use this product for enhanced sensitivity in serum-based assays.

Calibration and Control Microspheres. Calibration microspheres are microspheres of known fluorescent light intensities used to calibrate the settings for the classification and reporter channel for the Luminex systems. Control microspheres are microspheres that are used to verify the calibration and optical integrity for both the classification and reporter channels for the various systems.

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Software

xPONENT®. Our xPONENT Software is included in all of our xMAP instruments and enhances both ease-of-use and automation capabilities, expanding xMAP functionality in our core markets. The software suite incorporates important features, all designed to simplify laboratory workflow and increase productivity, including enhanced security (21 CFR Part 11 compliance and electronic signatures), integration capabilities that allow customers to transmit and receive data from Laboratory Information Systems (LIS/LIMS), integration with the most popular automated sample preparation systems, the ability to run magnetic bead applications and touch-screen capability. xPONENT is sold on new Luminex 100/200, FLEXMAP 3D, and MAGPIX Systems and is available as an upgrade to existing Luminex systems in the marketplace.

TDAS®. Our TDAS Software is an analysis program designed to complement our xTAG® Technology, which uses a proprietary universal tag system that allows for the development and optimization of nucleic acid assays. TDAS software simplifies workflow and increases productivity by helping to accurately identify pathogens associated with infectious diseases and genetic mutations. TDAS Software produces non-subjective results, which can be viewed in the software, integrated with LIS, and exported or printed into reports.

SYNCT™. Our SYNCT data management software solution compiles data from multiple ARIES® and xMAP Systems, assisting laboratories to better leverage their data to decrease laboratory costs and improve patient care.

IDEAS®. Our image analysis software for our Amnis flow cytometers provides detailed analysis of intensity, location, and co-location of probes. IDEAS offers powerful tools for high content, statistically robust analysis of images, as well as standard flow cytometry graphing tools and statistics for hundreds of morphological features in addition to intensity.

Clinical Diagnostic Assay Product Families

A product family consists of two or more assays that are focused on similar or related markets. Each assay consists of a combination of chemical and biological reagents and our proprietary technologies used to perform diagnostic and research assays on samples. As of February 25, 2019, the following product families are commercially available:

xTAG Assays and Product Family

This family of products includes infectious disease panels and genetic testing panels that utilize Luminex xMAP bead-based detection platforms in combination with proprietary molecular chemistries. The xTAG infectious disease IVD products enable our laboratory end users to identify the causative agent for respiratory and gastrointestinal infections, which are major causes of illness and mortality globally. The xTAG Assays for genetic testing include several IVD kits for cystic fibrosis (CF) genotyping and a number of pharmacogenetic assays that may be used to profile genetic mutations related to drug metabolism.

MultiCode Assays and Product Family

This product family includes our FDA-cleared HSV 1&2 Assay as well as a number of ASRs and other products. These products are generally designed to detect infectious agents in clinical samples using our proprietary MultiCode-RTx real-time PCR chemistry. We carry a diverse portfolio of bacterial, viral, fungal, and protozoan pathogen primers for global laboratory professionals.

ARIES® Assays and Product Family

ARIES® Cassettes. ARIES® cassettes are self-contained assay consumables designed to run a fully automated, sample to answer molecular assay on the ARIES® System. The cassettes make use of proprietary injection-molded parts, as well as MultiCode and other reagents, to perform automated extraction, purification, elution, amplification and testing of nucleic acid testing from a variety of different sample types.

This product family includes our FDA-cleared and CE-marked ARIES® HSV 1&2 Assay, ARIES® Flu A/B & RSV Assay, ARIES® GBS Assay, ARIES® Group A Strep Assay, ARIES® Bordetella Assay, and the ARIES® C. difficile Assay. Additional ARIES® assays are in development.

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VERIGENE Assays and Product Family

VERIGENE Cartridges. VERIGENE test cartridges are single-use, self-contained test units comprised of (i) a reagent pack, which is a microfluidic cassette that contains all of the hybridization reagents needed for a single test that also captures the waste materials generated during test processing, and (ii) a substrate holder, which contains a glass slide that serves as a solid support for the microarray used to capture targeted nucleic acids. Each test cartridge is designed for multiplex analyses of one patient sample.

This product family includes our FDA-cleared VERIGENE Bloodstream Infection tests, VERIGENE Gastrointestinal Infection tests, including the VERIGENE C. difficile Test and the VERIGENE Enteric Pathogens Test, and the VERIGENE Respiratory Pathogens Flex Test, as well as other VERIGENE and next generation assays in development.

In addition to the commercially available assays, we are an original equipment manufacturer (OEM) of custom reagents and instrumentation for certain of our customers.

Sales and Marketing

Our molecular diagnostic sales and marketing strategy is to expand the installed base and utilization of xMAP, xTAG, NxTAG®, ARIES®, and VERIGENE product lines. Our LTG is focused on generating recurring revenues from the sale of Luminex developed assays, microspheres and other consumables, as well as from royalties on kits and testing services developed or performed by partners. We have two key elements to our sales and marketing strategy: (i) marketing internally developed assays directly to end users and (ii) building and maintaining long-term relationships with our strategic partners. Our strategic partners include immune/clinical diagnostic, protein diagnostic, pharmaceutical and life sciences companies that develop applications and/or provide testing services using our xMAP technology platforms. Some partners also distribute xMAP Systems to their customers.

We sell the xTAG, NxTAG, MultiCode, ARIES® and VERIGENE product lines primarily through a direct sales channel. Building a direct relationship with customers is a critical component of our sales and marketing strategy to launch new, innovative products such as NxTAG Respiratory Pathogen Panel (RPP), ARIES® Systems and VERIGENE Systems. In addition, we market and sell our clinical diagnostics products to Group Purchasing Organizations (GPOs) and Integrated Healthcare Delivery Networks (IDNs). These efforts support and enable our selling efforts to individual laboratories, for example by contracting with GPOs to provide standardized pricing and terms for member hospitals.

Outside of our direct molecular diagnostic business, we continue to work with strategic partners as the primary distribution channel for our xMAP Systems, and we will continue to pursue new partnerships focusing on partners with market presence in the key partner segments described above. Some of our strategic partners develop application-specific kits for use on our xMAP Systems that they, in turn, sell to their customers, thereby generating royalties for us. Certain strategic partners also perform testing services for third parties using our xMAP products, which also result in royalty revenue. We also contract with distributors to purchase and resell xMAP Systems and consumables in geographic or application-specific areas not covered by strategic partners.

We update our LTG listing regularly to reflect partner consolidations resulting from mergers and acquisitions, commercial sales inactivity, as well as termination or expiration of existing non-performing partner agreements. As of December 31, 2018, we had 74 strategic partners, compared to 73 strategic partners as of December 31, 2017. During 2018, all 50 strategic partners with commercialized products utilizing xMAP Technology submitted royalties. As of December 31, 2018, all 50 of these strategic partners with commercialized products remain, of which 31 companies principally serve the clinical diagnostics market and 19 companies principally serve the life science research market.

Revenues from these commercialized, royalty-submitting, strategic partners constituted 58% of our revenues for 2018. We also believe our strategic partners provide us with complementary capabilities in product development, regulatory expertise and sales and marketing. By leveraging our strategic partners' assay development capabilities, customer relationships and distribution channels, we believe that we can continue to achieve measurable market penetration and product adoption. Our current partners are in various stages of development and commercialization of products that incorporate our technology.

We also serve as an OEM provider for certain strategic partners that choose to sell components of the xMAP product line as an embedded system under their own branding and marketing efforts.

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Our flow cytometry sales and marketing strategy is to become a global leader in flow cytometry, competing in all markets with disruptive and differentiated solutions by expanding our position in the research markets, building our diagnostic capabilities and increasing content generation. We expect that the growth of our flow cytometry business will be driven by our pipeline of new product launches and expanding our positions in the pharma, academic, diagnostics, and industrial markets, which should grow our recurring revenue in service, research and clinical reagents, and clinical trial solutions. In turn, we expect these accomplishments will drive geographic expansion in both established and developing markets.

We sell the Amnis and Guava Flow Cytometry Systems through a direct sales channel in developed markets in North America, EMEIA and APAC, and through distribution partners in emerging markets in Southeast Asia, Africa, and Latin America. The near-term goals of this business line are to strengthen the flow cytometry direct sales channel through integration into the Luminex sales function and expand our distribution networks in emerging markets. Our flow cytometry business has built healthy relationships with its customer base and has a reputation for quality customer support through its sales team and field application scientists, as well as technical service and instrument repair teams. We anticipate continuing to leverage these strengths to expand its installed base of instruments and concomitant recurring sales of reagents, software licenses, and services.

Customers

In each of the last three years, two customers or partners each accounted for more than 10% of our total revenues. LabCorp accounted for 15%, 20% and 20% of our total revenues and Thermo Fisher Scientific Inc. accounted for 14%, 15% and 13% of our total revenues in 2018, 2017 and 2016, respectively. No other customer or partner accounted for more than 10% of our total revenues in 2018, 2017 or 2016; however, Bio-Rad Laboratories, Inc. accounted for 6%, 6% and 7% of our total revenues in 2018, 2017 and 2016, respectively. The loss of any of these customers or partners (including LabCorp’s decision to move to an alternative vendor for women’s health products in 2018 discussed further on page 30) could have a material adverse effect or our business, financial condition and results of operations.

International Operations

We currently ship products to a number of customers outside the United States, primarily including customers in Canada, Europe and the Asia-Pacific region. For the annual periods ended December 31, 2018, 2017 and 2016, foreign shipments to customers totaled $54.1 million, $49.7 million and $47.9 million, respectively, representing 17%, 16% and 18%, respectively, of our total revenues for such periods. We have foreign subsidiaries in Canada, the Netherlands, the People’s Republic of China, Japan, and Hong Kong, which increase our international support, service and marketing capabilities. Sales to territories outside of the U.S. are primarily denominated in U.S. dollars. We believe that our activities in some countries outside the U.S. involve greater risk than our domestic business due to foreign economic conditions, exchange rate fluctuations, local commercial and economic policies and political uncertainties. See Note 16 to our Consolidated Financial Statements.

Technical Operations

Our Technical Operations Group provides technical assistance to our customers, our distributors, our strategic partners and their customers. Most of our technical operations personnel have experience as biologists, biochemists or electrical engineers and have extensive experience in academic, industrial and commercial settings. Cross training is a major focus, as is empowering group members to solve problems outside of their primary assignment.

Remote Support

Our technical support department assists users primarily through a toll-free hotline, internet interface and e-mail communications. We deliver “24/7” remote technical support with our staff based at our Austin, Northbrook and Toronto locations and from our European, Chinese and Japanese subsidiaries to better serve our customer base. Personnel assist our distributors, strategic partners and customers in inquiry and complaint management related to Luminex products, system implementation and development of their assays. A comprehensive software and database system is utilized to track customer interactions, follow trends and measure utilization. The information is categorized and presented to management for regular review.

Training

We offer comprehensive programs in basic system training, advanced assay development, instrument field service and technical support functions. A portion of our training material is web-based and available online. Customers have the option to receive training on-site at their location or locally, with our staff based at our Austin, Northbrook, European, Chinese or Japanese offices.

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Field Support

We currently have field service and field application personnel based across North America, Europe, China and Japan in areas of our more significant system concentration. In addition, several of our distributors and strategic partners provide their own field service and field application support. As we continue to expand our installed base, we believe a strong, reliable, efficient field support organization is crucial to maintaining a high level of customer satisfaction.

Research and Development

Our research and development groups work to develop next generation systems, chemistries, assays and software to provide new, innovative products to our customers. Our research and development expense for the years ended December 31, 2018, 2017 and 2016, was $47.2 million, $45.7 million and $48.7 million, respectively.

Our current research and development projects include:

- New platform and technology development

We are working on the development of the next generation, sample to answer, molecular diagnostic, automated VERIGENE II System. This involves the final design and development of the instrument, consumables and software as well as the development of a menu of assays for that system. We initiated clinical studies on the system and its first assay in 2018.

- New sample to answer menu development

We have a pipeline of new targeted and syndromic assays for use on the ARIES®, VERIGENE and the next generation VERIGENE II Systems. These automated assays are primarily in the area of infectious disease testing.

- Updated xMAP system

Our updated xMAP system, SENSIPLEX™, is nearing testing with partners and we expect will be ready for commercial launch by early 2020. Among other activities, our partners will need to validate the backwards capability of previously developed kits and plan their launches of new kits that will be able to take advantage of the increased sensitivity of this next generation xMAP System.

- Guava Next Gen

Our recently acquired flow cytometry research and development group has been working on a next generation Guava instrument that will provide researchers with simplified benchtop flow cytometry combined with an easy to use software interface. This new instrument will allow researchers to perform basic to advanced analysis with a consistent and reliable platform on the benchtop. These researchers will be in academia, pharma, government and biotechnology segments, and will be conducting research in areas such as immunology, cancer, bacteria, and others. This product will be a research use only product but is expected to launch worldwide by the end of 2019.

Manufacturing

We have approximately 124,000 square feet of leased manufacturing space, including space located at our principal executive offices in Austin, Texas (74,000 square feet), in Madison, Wisconsin (12,000 square feet), in Toronto, Canada (11,700 square feet), and in Northbrook, Illinois (26,300 square feet). In addition, in connection with the

closing of the acquisition of EMD Millipore Corporation's flow cytometry portfolio on December 31, 2018, we gained approximately 10,000 square feet of leased manufacturing space in Seattle, Washington.

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We initially certified our Quality Management System (QMS) to the ISO 9001:2000 standard and in 2010 updated our certification to ISO 9001:2008. ISO is an internationally recognized standard for quality management systems. Subsequent audits by the registrar have been and will continue to be carried out at regular intervals to ensure we are maintaining our system in compliance with ISO standards. Recertification is required every three years and we have been successfully recertified since obtaining our original ISO certification. Also, we have our QMS certified to the ISO 13485:2012 Quality Management Standard and the Canadian Medical Devices Regulation (CMDR). These standards include a special set of requirements specifically related to the supply of medical devices and related services. Additionally, we manufacture to current FDA "Good Manufacturing Practice" requirements and our QMS is implemented in accordance with FDA Quality System Regulations (21 CFR 820).

Supply Chain

We have historically purchased many of the components and raw materials used in our products from numerous suppliers worldwide. For reasons of quality assurance, sole source availability and cost-effectiveness, certain components and raw materials used in the manufacture of our products are available only from one supplier. We have worked closely with our suppliers to develop contingency plans to assure continuity of supply while maintaining high quality and reliability, and in some cases, we have established long-term supply contracts with our suppliers. Due to the high standards and FDA requirements applicable to the manufacturing of our products, we may not be able to quickly establish additional or replacement sources for certain components or materials. In the event that we are unable to obtain sufficient quantities of raw materials or components on commercially reasonable terms or in a timely manner, our ability to manufacture our products on a timely and cost-competitive basis may be compromised, which may have a material adverse effect on our business, financial condition and results of operations.

Instruments

Component suppliers and contract manufacturers provide certain components and component assemblies of our xMAP and ARIES® Systems. The remaining assembly and manufacturing of our systems are performed at our facilities in Austin, Texas and Northbrook, Illinois. The quality control and quality assurance protocols are all performed at our facilities. Parts and component assemblies that comprise our technology systems are obtained from a number of sources. We have identified alternate sources of supply for several of our strategic parts and component assemblies. Additionally, we have entered into supply agreements with most of our suppliers of strategic parts and component subassemblies to help ensure component availability and flexible purchasing terms with respect to the purchase of such components. As of December 31, 2018, a total of 15,979 Luminex multiplexing analyzers have been shipped since 1999, some of which may be retired or otherwise not in use.

Microspheres

We procure our undyed, standard MicroPlex® microspheres and manufacture our magnetic MagPlex® carboxylated polystyrene microspheres. We synthesize our dyes and manufacture our dyed microspheres using a proprietary method in our Austin, Texas manufacturing facility in large lots. We dye the microspheres with varying intensities of red and near infrared dyes to produce our distinctly colored microsphere sets. We currently purchase the standard polystyrene microspheres from one supplier, in accordance with a supply agreement. We believe this agreement will help ensure microsphere availability and flexible purchasing terms with respect to the purchase of such microspheres. While we believe the microspheres will continue to be available from our supplier in quantities sufficient to meet our production needs, we believe our in-house manufacturing capabilities along with other potential suppliers would provide sufficient microspheres for us if given adequate lead-time to manufacture the microspheres to our specifications.

Assays and Reagents

Component suppliers and contract manufacturers produce certain components of our developed reagents. The remaining assembly and manufacturing of our on-market kits are performed at one of our facilities in Austin, Texas, Toronto, Canada, Madison, Wisconsin, Northbrook, Illinois, or Seattle, Washington. The quality control and quality assurance protocols are all performed at our facilities. Reagents, consumables and other raw material that comprise our kits are obtained from a number of sources.

In addition to developed assay kits, increasing regulatory requirements coupled with rising demand for new clinical applications are driving demand for laboratory developed tests. Our proprietary technologies and platforms offer a unique combination of flexibility and throughput, as our systems' open architecture, software and standard protocols allow our customers the ability to use our proprietary reagents to validate and verify a new test, while being able to utilize the same system to handle increasing volumes once the assay is commercialized.

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Competition

We design our xMAP Systems and consumables for use by customers across the various segments of the life sciences, pharmaceutical and clinical diagnostic industries. Our xTAG, NxTAG, MultiCode, ARIES® and VERIGENE products are developed specifically for the molecular diagnostic segment. Our competition includes companies marketing conventional testing products based on established technologies such as ELISA, real-time PCR, mass spectrometry, gene sequencing, biochips, arrays and flow-based technologies, as well as next generation sequencing and companies developing their own advanced testing technologies.

The pharmaceutical industry is a large market for the genomic, protein and high-throughput screening applications supported by xMAP Technology. In each application area, Luminex faces a different set of competitors. Genomic and protein testing can be performed by products available from Affymetrix, Inc. (a Thermo Fisher Scientific Inc. brand), Life Technologies Corporation (a Thermo Fisher Scientific Inc. brand), Becton, Dickinson and Company, Illumina, Inc., Qiagen N.V., Meso Scale Discovery (a division of Meso Scale Diagnostics LLC), Quanterix Corporation, PerkinElmer, Inc., Bio-Rad Laboratories, Inc., and others.

Our diagnostic market competitors include, among others, Abbott Laboratories, Life Technologies Corporation (a Thermo Fisher Scientific Inc. brand), BioFire Diagnostics, LLC (a bioMérieux company), Cepheid (a Danaher Corporation company), GenMark Dx, Roche Diagnostics, Siemens Medical Solutions, Hologic, Inc., Alere (now part of Abbott Laboratories), Quidel Corporation, Focus Diagnostics (DiaSorin S.p.A), T2 Biosystems, Inc., Accelerate Diagnostics, Inc., Meridian Bioscience, Inc., and Illumina, Inc. Some of these companies have technologies that can run a variety of established assays. In addition, certain of these companies offer integrated systems and laboratory automation that are designed to meet the need for improved work efficiencies in the clinical laboratory.

Competition within the academic biomedical research market is highly fragmented. There are hundreds of suppliers to this market including, among others, Amersham Pharmacia Biotech, a part of GE Healthcare, Life Technologies Corporation (a Thermo Fisher Scientific Inc. brand) and Becton, Dickinson and Company.

Intellectual Property

To establish and protect our proprietary technologies and products, we rely on a combination of patent, copyright, trademark and trade secret laws and confidentiality agreements. We have filed for registration or obtained registration for trademarks used with our products and key technologies.

We have implemented a strategy designed to optimize our intellectual property rights. For core intellectual property, we are pursuing patent coverage in the United States and those foreign countries that correspond to the majority of our current and anticipated customer base. We currently own 728 issued patents worldwide directed to various aspects and applications of our products and technology, including 243 issued patents in the United States. Other countries in which we have issued patents directed to various aspects and applications of our products and technology include, among others, France, Germany, the United Kingdom, Australia, Japan, Netherlands, Canada, Hong Kong and China. Our patent portfolio also includes 160 pending patent applications in the United States and other foreign jurisdictions. We believe our patents and pending patent applications provide, or will provide, protection for systems and technologies that allow real-time multiplexed analytical techniques for the detection and quantification of many analytes from a single sample. We also hold patents covering the fluorescently dyed, magnetically responsive microspheres and patents covering digital over-sampling to measure the area of a fluorescence pulse instead of “peak detection,” giving increased sensitivity with no lost events. In addition, multiple granted patents and pending applications describe aspects of Multicode technology, xTAG technology, nanoparticle technology, the ARIES® and VERIGENE Systems, NxTAG technology, imaging flow cytometry technology and capillary flow cytometry technology.

The source code for our proprietary software is protected as a trade secret and/or as a copyrighted work. Aspects of this software also are covered by an issued patent.

We also rely on trade secret protection of our intellectual property. We attempt to protect our trade secrets by entering into confidentiality agreements with strategic partners, third parties, employees and consultants. Our employees and third-party consultants also sign agreements requiring that they assign to us their interests in inventions and original works of expression and any corresponding patents and copyrights arising from their work for us. See Item 1A, Risk Factors - “The property rights we rely upon to protect the technologies underlying our products may not be adequate to maintain market exclusivity. Inadequate intellectual property protection could enable third parties to exploit our technologies or use very similar technologies and could reduce our ability to distinguish our products in the market.”

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Government Regulation

Our products are generally considered medical devices and are subject to regulation by numerous government agencies, including the FDA and similar agencies outside the United States. To varying degrees, each of these agencies require us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our medical devices. Our business is also affected by the United States and foreign patient privacy laws, cost containment initiatives and environmental health and safety laws and regulations. The primary laws and regulations that are particularly relevant to our business are described below.

Food and Drug Administration

In general, the products that we manufacture are considered to be medical devices and are subject to regulation in the United States by the U.S. Food and Drug Administration, or the FDA. We also manufacture versions of the Luminex instruments for use with diagnostic assay kits that are available through our strategic partners. For FDA purposes, the Luminex systems are considered components of our partners' kit products. Kits manufactured by our strategic partners used in conjunction with our technology, may be subject to clearance or approval requirements and other FDA regulations.

The FDA classifies medical devices into one of three classes on the basis of the intended use of the device, the risk associated with the use of the device for that indication, as determined by the FDA, and on the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices, which have the lowest level of risk associated with them, are subject to general controls. Class II devices are subject to general controls and special controls, including performance standards. Class III devices, which have the highest level of risk associated with them, are subject to general controls and premarket approval. Most Class I devices and some Class II devices are exempt from a requirement that the manufacturer submit a premarket notification, or 510(k), and receive clearance from the FDA which is otherwise a premarketing requirement for a Class II device. Class III devices may not be commercialized until a premarket approval application, or PMA, is submitted to and approved by the FDA.

510(k) Clearance Pathway

To obtain 510(k) clearance, a sponsor must submit to the FDA a premarket notification demonstrating that the device is substantially equivalent, or SE, to a device legally marketed in the U.S. for which a PMA was not required. The FDA is supposed to make a SE determination within 90 days of FDA's receipt of the 510(k), but it often takes longer if the FDA requests additional information. Most 510(k)s do not require supporting data from clinical trials, but the FDA may request such data. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or possibly a pre-market approval.

De Novo Classification

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure.

This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and

Drug Administration Safety and Innovation Act of 2012 (“FDASIA”), a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the de novo application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

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Premarket Approval Pathway

A PMA must be submitted if a new device cannot be cleared through the 510(k) process. The PMA process is generally more complex, costly and time consuming than the 510(k) process. A PMA must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. After a PMA is sufficiently complete, the FDA will accept the application for filing and begin an in depth review of the submitted information. By statute, the FDA has 180 days to review the accepted application, although, review of the application generally can take between one and three years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Although the FDA is not bound by the advisory panel decision, the panel's recommendations are important to the FDA's overall decision making process. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with its quality system regulations, or QSRs. New premarket approval applications or premarket approval application supplements are also required for product modifications that affect the safety and efficacy of the device.

Clinical Trials

Clinical trials are usually required to support a PMA and are sometimes required for a 510(k). In the U.S., if the device is determined to present a "significant risk," the manufacturer may not begin a clinical trial until it submits an investigational device exemption application, or IDE, and obtains approval of the IDE from the FDA. These clinical trials are also subject to the review, approval and oversight of an institutional review board, or IRB, at each clinical trial site. The clinical trials must be conducted in accordance with the FDA's IDE regulations and good clinical practices. A clinical trial may be suspended by FDA, the sponsor or an IRB at its institution at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the trial. Even if a clinical trial is completed, the results may not demonstrate the safety and efficacy of a device to the satisfaction of the FDA, or may be equivocal or otherwise not be sufficient to obtain approval of a device.

FDA Enforcement

After a medical device is placed on the market, numerous regulatory requirements apply. These include among other things:

- establishment registration and device listing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and the FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses and other requirements related to promotional activities;
- medical device reporting regulations, which require that manufactures report to the FDA if their device may have caused or contributed to a death or serious injury, or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;

- corrections and removal reporting regulations, which require that manufactures report to the FDA field

corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FD&C Act that may present a risk to health; and

- post market surveillance regulations, which apply to certain Class II or III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

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To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre scheduled and unannounced inspections by the FDA. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include sanctions, including but not limited to, warning letters; fines, injunctions, consent decrees and civil penalties; recall or seizure of the device; operating restrictions, partial suspension or total shutdown of production; refusal to grant 510(k) clearance or PMA approvals of new devices; withdrawal of 510(k) clearance or PMA approvals; and civil or criminal prosecution.

Research Use Only Products

Our products are currently intended for research use only, or RUO, applications, although our customers may use our products to develop their own products that are subject to regulation by the FDA. Although most products intended for RUO are not currently subject to clearance or approval by the FDA, RUO products fall under the FDA's jurisdiction if they are used for clinical rather than research purposes. Consequently, our products are labeled "For Research Use Only.

On November 25, 2013, the FDA issued Final Guidance for Industry and Food and Drug Administration Staff on "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only," or, the RUO/IUO Guidance. The purpose of an FDA guidance document is to provide the FDA's current thinking on when IVD products are properly labeled for RUO or for IUO, but as with all FDA guidance documents, this guidance does not establish legally enforceable responsibilities and should be viewed as recommendations unless specific regulatory or statutory requirements are cited. The RUO/IUO Guidance explains that the FDA will review the totality of the circumstances when evaluating whether equipment and testing components are properly labeled as RUO. Merely including a labeling statement that a product is intended for research use only will not necessarily exempt the device from the FDA's 510(k) clearance, premarket approval, or other requirements, if the circumstances surrounding the distribution of the product indicate that the manufacturer intends its product to be used for clinical diagnostic use. These circumstances may include written or verbal marketing claims or links to articles regarding a product's performance in clinical applications, a manufacturer's provision of technical support for clinical validation or clinical applications, or solicitation of business from clinical laboratories, all of which could be considered evidence of intended uses that conflict with RUO labeling. Consequently, our products are labeled "For Research Use Only" and meet the intent of the RUO/IUO Guidance.

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

Laboratories that purchase certain of our products are subject to extensive regulation under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), CLIA is a set of federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States (with the exception of clinical trials and basic research). A clinical laboratory is defined by CLIA as any facility that performs laboratory testing on specimens obtained from humans for the purpose of providing information for health assessment and for the diagnosis, prevention, or treatment of disease."). CLIA requires laboratories to meet specified standards in areas such as personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. such laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification also is a prerequisite to be eligible to bill state and federal health care programs, as well as many private insurers, for laboratory testing services.

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As a condition of CLIA certification, laboratories are subject to survey and inspection every other year, in addition to being subject to additional random inspections. The biennial survey is conducted by the Centers for Medicare & Medicaid Services ("CMS"), a CMS agent (typically a state agency), or, a CMS approved accreditation organization. High complexity, CLIA-certified laboratories frequently develop testing procedures to provide diagnostic results to customers. These tests have been traditionally offered by nearly all complex laboratories for the last few decades as Laboratory Developed Tests, or LDTs, which are subject to CMS oversight through its enforcement of CLIA. The FDA also has claimed that it has regulatory authority over LDTs, but has not exercised enforcement with respect to most LDTs offered by high complexity laboratories, and not sought to require these laboratories to comply with FDA regulations regarding medical devices. During 2010, the FDA publicly announced that it has decided to exercise regulatory authority over these LDTs, and that it plans to issue guidance to the industry regarding its regulatory approach. At that time, the FDA indicated that it would use a risk-based approach to regulation and would direct more resources to tests with wider distribution and with the highest risk of injury, but that it will be sensitive to the need to not adversely impact patient care or innovation. In September 2014, the FDA announced its framework and timetable for implementing this guidance. On November 18, 2016, the FDA announced it would not release final guidance at this time and instead would continue to work with stakeholders, the new administration and Congress to determine the right approach. On January 3, 2017, the FDA released a discussion paper outlining a possible risk-based approach for FDA and CMS oversight of LDTs. Later in 2017, the FDA indicated that Congress should enact legislation to address improved oversight of diagnostics, including LTDs, rather than the FDA addressing the issue through administrative proposals. We cannot predict the ultimate timing or form of any such guidance or regulation or their potential impact. If adopted, such a regulatory approach by the FDA may lead to an increased regulatory burden, including additional costs and delays in introducing new tests. While the ultimate impact of the FDA's approach is unknown, it may be extensive and may result in significant change.

Radiological Health Regulations

Certain of our instruments use lasers to detect assay results. Therefore, we are required to ensure that these products comply with FDA regulations pertaining to the performance of laser products. The Radiation Control for Health and Safety Act, administered by the FDA, imposes performance standards and record keeping, reporting, product testing and product labeling requirements for devices that emit radiation. These regulations are intended to ensure the safety of laser products by establishing standards to prevent exposure to excessive levels of laser radiation. There can be no assurance that the FDA will agree with our interpretation and implementation of these regulations.

Foreign Jurisdictions

Medical device laws and regulations are also in effect in many countries outside of the United States ranging from comprehensive pre-approval requirements for medical products, to simpler requests for product data or certification. The number and scope of these requirements is increasing. There can be no assurance that we, and our strategic partners, will be able to obtain any approvals that may be required to market xMAP or other technology products outside the United States. In addition, we may incur significant initial and/or ongoing costs in obtaining or maintaining our foreign regulatory approvals. Further, the export by us of products that have not yet been cleared for domestic commercial distribution is subject to FDA and other export requirements and/or restrictions.

We have agreements relating to the sale of our products to government entities and, as a result, we are subject to various statutes and regulations that apply to companies doing business with the government. A failure to comply with these regulations could result in suspension of these contracts, or administrative or other penalties, and could have a material adverse effect on our ability to compete for future government contracts and programs.

We produce CE marked products, which are subject to a number of different European Union (EU) Directives, including, but not limited to, the In Vitro Diagnostic Devices Directive (98/79/EC) (IVDD). CE marking of our

products is currently by self-declaration, not issued by a third party, based on the intended uses of our products. A product that is not CE marked is automatically considered to be non-compliant. The law is enforced through market surveillance by appointed national enforcement agencies. Imported products are checked for compliance at customs offices.

No in vitro device or accessory may be placed on the market or put into service unless it satisfies the essential requirements set forth in the IVDD. Devices considered to meet the essential requirements must bear the CE marking of conformity, placed by the manufacturer, when introduced on the market. A manufacturer placing devices on the market in its name must notify its national competent authorities.

There can be no assurance that the EU member states will agree with our interpretation and implementation of these regulations as it pertains to classification of our products. The failure by us or our strategic partners to comply with the IVDD could have a material adverse effect on our business.

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The State Food and Drug Administration, P.R. China (SFDA), is the government regulation authority in charge of safety management of drug, food, health food and cosmetics for the People's Republic of China. The SFDA issues certificates that are required for registration and approval to import our products into China. Certificates are also subject to periodic recertification requirements. We have received certificates for the "Luminex System," which combines the Luminex 100 and Luminex 200 into one product, and for our MAGPIX System.

Failure by us, or our strategic partners, to comply with applicable current federal, state and foreign medical product laws and regulations could have a material adverse effect on our business. Federal, state and foreign regulations regarding the manufacture and sale of medical devices and components of such devices are continually subject to future changes. We cannot predict what impact, if any, such changes might have on our business, but any such change could have a material impact.

WEEE

The European Community Council Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) outlines the responsibility for the disposal of waste electrical and electronic equipment. Compliance with WEEE is placed with the manufacturers of such equipment. Those manufacturers are required to establish an infrastructure for collecting WEEE, in such a way that users of electrical and electronic equipment from private households should have the ability of returning WEEE at least free of charge. All Luminex-manufactured equipment is in compliance with this directive. Since August 13, 2005, we have been in compliance with the requirements regarding the labeling and disposal of our products containing electronic devices in each of the EU member states where our regulated products are distributed.

RoHS

RoHS stands for "The Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment" and implements EU Directive 2002/95, which bans the placing on the EU market of new electrical and electronic equipment containing more than agreed levels of lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl and polybrominated diphenyl ether flame retardants.

The Directive directly affects producers who manufacture or assemble electrical or electronic equipment in the EU, importers of electrical or electronic equipment from outside the EU and companies that re-brand electric producers as their own. The Directive applies to electrical and electronic equipment falling under the categories 1, 2, 3, 4, 5, 6, 7 and 10 set out in Annex IA of the WEEE Directive (2002/96/EC). Equipment categories 8 and 9 defined in the WEEE Directive are currently outside the scope of the RoHS Directive. Luminex IVD equipment is classified as category 8 (Medical Devices) in Annex IA of the WEEE Directive, which is not covered within the scope of the RoHS Directive. Luminex research equipment is classified as category 9 (Monitoring and Control Instruments) in Annex IA of the WEEE Directive, which is not covered within the scope of the RoHS Directive.

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Environmental

We are subject to federal, state and local laws and regulations relating to the protection of human health and the environment. In the course of our business, we are involved in the handling, storage and disposal of certain chemicals and biohazards. The laws and regulations applicable to our operations include provisions that regulate the discharge of materials into the environment. Some of these environmental laws and regulations impose "strict liability," rendering a party liable without regard to negligence or fault on the part of such party. Such environmental laws and regulations may expose us to liability for environmental contamination, including remediation costs, natural resource damages and other damages as a result of the conduct of, or conditions caused by, us or others or for acts that were in compliance with all applicable laws at the time such acts were performed. In addition, where contamination may be present, it is not uncommon for neighboring landowners and other third parties to file claims for personal injury, property damage and recovery of response costs. Although it is our policy to use generally accepted operating and disposal practices in accordance with applicable environmental laws and regulations, hazardous substances or wastes may have been disposed or released on, under or from properties owned, leased or operated by us or on, under or from other locations where such substances or wastes have been taken for disposal. These properties may be subject to investigation, remediation and monitoring requirements under federal, state and local environmental laws and regulations. We believe that our operations are in substantial compliance with applicable environmental laws and regulations. However, failure to comply with these environmental laws and regulations may result in the imposition of administrative, civil and criminal penalties or other liabilities. We do not believe that we have been required to expend material amounts in connection with our efforts to comply with environmental requirements or that compliance with such requirements will have a material adverse effect upon our capital expenditures, results of operations or competitive position. Because the requirements imposed by such laws and regulations may frequently change and new environmental laws and regulations may be adopted, we are unable to predict the cost of compliance with such requirements in the future, or the effect of such laws on our capital expenditures, results of operations or competitive position. Moreover, the modification or interpretation of existing environmental laws or regulations, the more vigorous enforcement of existing environmental laws or regulations or the adoption of new environmental laws or regulations may also negatively impact our strategic partners, which in turn could have a material adverse effect on us and other similarly situated component companies.

Other Government Regulations

Our operations in the United States are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and state and federal marketing compliance laws. These laws may impact our operations directly or indirectly through our customers and may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. We are also subject to statutes in foreign jurisdictions that prohibit commercial bribery and certain activities with customers or potential customers. The laws that may affect our ability to operate include the following foreign laws, federal laws and their counterparts at the state level in addition to various implementing regulations:

- the federal Anti-Kickback Statute and state anti-kickback prohibitions;
- the federal physician self-referral prohibition, commonly known as the Stark Law, and state equivalents;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended, and implementing privacy, security and breach notification regulations;
- the Civil Monetary Penalties Law and related exclusion provisions;
- the federal False Claims Act and state equivalents;
- the U. K. Bribery Act of 2010;
- the Foreign Corrupt Practices Act, which applies to our international activities; and
- the Physician Payment Sunshine Act.

Other

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (Affordable Care Act), provides for a medical device excise tax of 2.3% of the sale price on non-exempt medical devices. The Internal Revenue Service implemented this tax on manufacturers, producers and importers in 2013, but the tax was subject to a moratorium beginning in 2016 which Congress has effectively extended through December 31, 2019. The medical device tax has not had, nor do we expect it to have, a material impact on our operations.

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The Affordable Care Act resulted in extensive changes across the healthcare system, affecting coverage, delivery and reimbursement of services. However, there is substantial uncertainty regarding the future of the Affordable Care Act. The law has been subject to legislative and regulatory changes and court challenges, and the presidential administration and certain members of Congress have expressed their intent to repeal or make significant changes to the Affordable Care Act, its implementation or its interpretation. Effective January 2019, Congress eliminated the financial penalty associated with the individual mandate to maintain health insurance coverage. Because the penalty associated with the individual mandate was eliminated, a federal court in Texas ruled in December 2018 that the entire Affordable Care Act was unconstitutional, however, the law remains in place pending appeal. It is possible that the Affordable Care Act, uncertainty regarding its repeal, the ultimate outcome and impact of court challenges, significant changes to the law or other health reform efforts, such as single-payor proposals, will adversely affect our customers and strategic partners, which could cause them to reduce or delay the purchase of our systems or to demand reduced fees.

Employees

As of February 25, 2019 and December 31, 2018, respectively, we had a total of 1,141 and 988 employees and contract employees, as compared with 896 as of December 31, 2017. The year over year increase is primarily the result of the Acquisition, which was completed on December 31, 2018. None of our employees are represented by a collective bargaining agreement, and we have not experienced any work stoppage. We believe that relations with our employees are good.

Seasonality

Worldwide sales, including U.S. sales, do not reflect any significant degree of seasonality; however, sales of our Respiratory Viral products have demonstrated seasonal fluctuations consistent with the onset and decline of influenza-like illnesses.

Financial information relating to our business for the years ended December 31, 2018, 2017 and 2016 can be found in Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Item 8 “Financial Statements and Supplementary Data.”

Available Information

Our shares of common stock are traded on the Nasdaq Global Select Market under the symbol “LMNX.” Our principal executive offices are located at 12212 Technology Blvd., Austin, Texas 78727, and our telephone number is (512) 219-8020. Our website address is www.luminexcorp.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, are available free of charge through our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission, or the SEC. Information contained or accessible on our website is not incorporated by reference into this report and such information should not be considered to be part of this report except as expressly incorporated herein. The public may read and copy these materials on the SEC’s website at www.sec.govU. The SEC’s website contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Luminex was incorporated under the laws of the State of Texas in May 1995 and reincorporated in the State of Delaware in February 2000.

Executive Officers of the Registrant as of February 25, 2019

Name	Age	Position
Nachum Shamir	65	President and Chief Executive Officer
Harriss T. Currie	57	Chief Financial Officer, Senior Vice President, Finance and Treasurer
Todd C. Bennett	49	Senior Vice President, Global Sales and Customer Operations
Chuck Collins	42	Senior Vice President, Research and Development
Nancy M. Fairchild	65	Senior Vice President, Human Resources
Randall J. Myers	57	Senior Vice President, Global Manufacturing and Quality
Richard W. Rew II	51	Senior Vice President, General Counsel and Corporate Secretary
Eric S. Shapiro	55	Senior Vice President, Global Marketing

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Nachum Shamir. Mr. Shamir joined the Company on October 14, 2014 as President and Chief Executive Officer and was elected to our Board. From 2006 to 2014, Mr. Shamir was the President, Chief Executive Officer and Director of Given Imaging Ltd. (Given), a developer of the PillCam capsule and manufacturer and marketer of diagnostic products for the visualization and detection of disorders of the gastrointestinal tract, which was acquired by Covidien PLC in early 2014. Mr. Shamir currently serves on the board of directors of Strata Skin Sciences, Inc. (Nasdaq: SSKN); a medical technology company which focuses on the dermatology market. Mr. Shamir holds a Bachelor of Science from the Hebrew University of Jerusalem and a Masters of Public Administration from Harvard University.

Harriss T. Currie. Mr. Currie served the Company as Vice President, Finance, Treasurer and Chief Financial Officer since October of 2002 and was appointed Senior Vice President, Finance (as well as Chief Financial Officer and Treasurer) of the Company in March 2013. Since joining the Company in November of 1998, Mr. Currie previously served in the capacities of Controller and Treasurer. Prior to joining us, he was employed as the chief financial officer, secretary and treasurer of SpectraCell Laboratories, a specialized clinical testing laboratory company, from 1993 to 1998 where he also served as vice president of finance for two subsidiary companies. Mr. Currie earned his B.B.A. from Southwestern University and his M.B.A. in Finance and Marketing from the University of Texas at Austin. Prior to returning to graduate school for his M.B.A., Mr. Currie was a certified public accountant with Deloitte & Touche LLP.

Todd C. Bennett. Mr. Bennett joined the Company in October 2012 as General Manager, Americas. Mr. Bennett was promoted to Vice President, Global Sales and Customer Operations in July 2015 and to Senior Vice President, Global Sales and Customer Operations in November 2016. From January 2007 through March 2012, Mr. Bennett was the Vice President of Sales and then promoted to Vice President of Commercial Operations at Immucor, Inc., a provider of transfusion and transplantation products, where he was responsible for Commercial Operations (Sales, Global Marketing, Customer Service functions). Prior to Immucor, Mr. Bennett held various commercial leadership roles at Roche Diagnostics and Abbott Laboratories dating to 1994. Mr. Bennett holds a B.S. in Business Administration with an emphasis in finance from the Max M. Fisher College of Business at The Ohio State University in Columbus, Ohio.

Chuck Collins. Dr. Collins joined the Company in January 2006 as Senior Scientist. Dr. Collins was promoted to Director, Advanced Technology Group in January of 2008, and to Senior Director, Advanced Technology Group in August 2010. Dr. Collins then expanded his role with a promotion to Vice President, Systems R&D in May of 2012 and to Senior Vice President, R&D in January 2018. From August 2002 to January 2006, Dr. Collins was a Research Scientist at The U.S. Army Research Laboratory, developing ultraviolet LEDs, laser diodes, and photodetectors. Dr. Collins earned his BS in Electrical Engineering from Trinity University and received his Masters and PhD degrees in Electrical Engineering from The University of Texas at Austin.

Nancy M. Fairchild. Ms. Fairchild joined the Company as Senior Director, Human Resources in March 2010. She was promoted to Vice President, Human Resources in August 2012 and to Senior Vice President, Human Resources in January 2015. Prior to joining the Company, Ms. Fairchild served from 2006 to 2010 as Chief Administrative Officer and Vice President of Human Resources and Organizational Development for the Electric Reliability Council of Texas which provides the energy grid services for Texas. In this role she managed Strategic Planning, Project Management, Facilities and Human Resources. Earlier in her career, she served as Vice President, Human Resources for Esoterix, Inc., an international healthcare company specializing in laboratory services, from 2001 to 2006, the Senior Vice President of Human Resources for Southern Union Company, a large natural gas conglomerate, from 1989 to 2001, and President of EnergyWorX, a training subsidiary, from 1996 to 2000. Ms. Fairchild is currently a member of the Board of Directors and Chair of the Audit Committee for Workforce Solutions, a local workforce development board in Texas, representing the biotech sector. She graduated with highest honors from Texas State University with a B.S. degree in Math Education and an M.S. degree in Counseling.

Randall J. Myers. Mr. Myers joined the Company as Senior Vice President, Global Manufacturing and Quality, in March 2015. Prior to joining the Company, Mr. Myers accepted an early retirement from Applied Materials, Inc. (Applied Materials), a supplier of equipment services and software to enable the manufacture of semiconductor, flat panel display, glass, WEB and solar products, in 2012 and had been consulting in supply chain and manufacturing operations since that time. Prior to his retirement from Applied Materials, Mr. Myers held various positions at Applied Materials in manufacturing and operations from 1995-2012. In his final position with Applied Materials, Mr. Myers was Vice President of the Silicon Systems Group Global Planning & Business Operations. Mr. Myers attended Kettering University where he obtained a B.S. in Electrical Engineering.

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Richard W. Rew II. Mr. Rew joined the Company as Senior Vice President, General Counsel and Corporate Secretary in March 2015. Prior to joining the Company, Mr. Rew served as Senior Vice President, General Counsel and Secretary at ArthroCare Corporation (ArthroCare), a medical device company, from December 2008 until it was acquired by Smith & Nephew in 2014. Mr. Rew joined ArthroCare in 2006 as its Vice President, Legal Affairs. Mr. Rew previously served as General Counsel of Activant Solutions Inc. from 2000 to 2006 and as General Counsel of EZCORP, Inc. from 1996 to 2000. Mr. Rew earned a B.A. in the Plan II Honors Program from the University of Texas at Austin and a J.D. from the University of Oklahoma College of Law. Mr. Rew is a member of the State Bar of Texas.

Eric S. Shapiro. Mr. Shapiro joined Luminex in October 2015 as the Vice President of Global Marketing, and was promoted to Senior Vice President, Global Marketing in February 2018. Prior to joining the Company on a full-time basis, Mr. Shapiro was the Principal at ESS Strategic Consulting, LLC, which he founded in 2014. In his role there, he worked on a variety of global strategic and operational projects, including serving as the General Manager for the Market Launch of ARIES® and NxTAG® RPP, from May 2015 to September 2015. Mr. Shapiro has previously served as a Vice President of Marketing for Given, from 2009 to 2014, and held numerous leadership positions at Kinetic Concepts, Inc., from 1993 to 2007, including Vice President of Marketing, Vice President of Patient Administration, Director of Corporate Development, and Director of Mergers and Acquisitions. Mr. Shapiro began his career working in both office and hospital-based Sales positions with Merrell Dow and Marion Merrell Dow. Mr. Shapiro holds a B.S. degree from Syracuse University, with an emphasis in Marketing and Telecommunications Management, and an M.B.A. from the J.L. Kellogg Graduate School of Management, with an emphasis in Marketing, Healthcare, Organizational Behavior, and Economics.

ITEM 1A. RISK FACTORS

The life sciences and diagnostics industries are highly competitive and subject to rapid technological change, and we may not have the technologies and resources necessary to compete successfully.

We compete with companies in the United States and abroad that are engaged in the development and production of similar products. We will continue to face intense competition from existing competitors and other companies seeking to develop and commercialize new technologies. Many of our competitors have access to greater financial, technical, scientific, research, marketing, sales, distribution, service and other resources than we do and may have longer operating histories or more recognizable brand names. These companies may develop technologies that are superior alternatives to our technologies or may be more effective at commercializing their technologies in products.

The life sciences and diagnostics industries are characterized by rapid and continuous technological innovation. We may need to develop new technologies for our products to remain competitive. One or more of our current or future competitors could render our present or future products or those of our partners obsolete or uneconomical by technological advances, including the introduction or existence of, competing products or technologies that may be more effective, cheaper or easier to use than our products and technologies. In addition, the introduction or announcement of new products by us or others could result in a delay of or decrease in sales of existing products as we await regulatory approvals, while customers evaluate these new products, or if customers choose to purchase the new products instead of legacy products. We may also encounter other problems in the process of delivering new products to the marketplace such as problems related to design, development, supply chain or manufacturing of such products, and as a result we may be unsuccessful in selling such products. Our future success depends on our ability to compete effectively against current technologies, as well as to respond effectively to technological advances by developing and marketing products that are competitive in the continually changing technological landscape.

Several companies provide systems and reagents for DNA amplification or detection. Life Technologies Corporation (a Thermo Fisher Scientific Inc. brand) and F. Hoffman-La Roche Ltd. (Roche) sell systems integrating DNA

amplification and detection (sequence detection systems) to the commercial market. Life Technologies Corporation (a Thermo Fisher Scientific Inc. brand), Roche, Abbott Laboratories, Becton Dickinson and Company, Danaher Corporation, Qiagen N.V., Hologic, Inc., Meridian Bioscience, Inc., bioMérieux S.A., Illumina, Inc. and Quidel Corporation sell sequence detection systems, some with separate robotic batch DNA purification systems, and they also sell reagents to the clinical diagnostics market. Other companies offer molecular diagnostic tests. Additionally, we anticipate that in the future, additional competitors will emerge that offer a broad range of competing products, including increasing adoption of competitive products based on mass spectrometry and next generation sequencing test technologies.

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If we do not introduce new products in a timely manner, we may lose market share and be unable to achieve revenue growth targets.

We sell many of our products in industries characterized by rapid technological change, frequent new product and service introductions and evolving customer needs and industry standards. Many of the businesses competing with us in these industries have significant financial and other resources to invest in new technologies, substantial intellectual property portfolios, substantial experience in new product development, regulatory expertise, manufacturing capabilities and established distribution channels to deliver products to customers. Our products could become technologically obsolete over time, or we may invest in technologies that do not lead to revenue growth or continue to sell products for which the demand from our customers is declining, in which case we may lose market share or not achieve our revenue growth targets. The success of our new product offerings will depend upon several factors, including our ability to:

- accurately anticipate customer needs;
- innovate and develop new technologies and applications;
- obtain required regulatory clearances;
- successfully commercialize new technologies in a timely manner;
- price our products competitively, and manufacture and deliver our products in sufficient volumes and on time; and
- differentiate our offerings from our competitors' offerings.

Many of our products are used by our customers to develop, test and manufacture their products. We must anticipate industry trends and consistently develop new products to meet our customers' expectations. In developing new products, we may be required to make significant investments before we can determine the commercial viability of the new product. If we fail to accurately foresee our customers' needs and future activities, we may invest heavily in research and development of products that do not lead to significant revenue. We may also suffer a loss in market share and potential revenue if we are unable to commercialize our products in a timely and efficient manner.

We may be unsuccessful in implementing our acquisition strategy. We may face difficulties integrating acquired entities with our existing businesses. Our business may be harmed by prior or future acquisitions.

Acquisitions of assets or entities designed to accelerate the implementation of our strategic plan are an important element of our long-term strategy. We may be unable to identify and complete appropriate future acquisitions in a timely manner, or at all, and no assurance can be provided that the market price of potential business acquisitions will be acceptable. In addition, many of our competitors have greater financial resources than we have and may be willing to pay more for these businesses or selected assets. In the future, should we identify suitable acquisition targets, we may be unable to complete acquisitions or obtain the financing, if necessary, for these acquisitions on terms favorable to us. Potential acquisitions pose a number of risks, including, among others, that:

- we may not be able to accurately estimate the financial effect of acquisitions on our business;
- future acquisitions may require us to incur debt or other obligations, issue additional securities, incur large and immediate write-offs, issue capital stock potentially dilutive to our stockholders or spend significant cash, or may negatively affect our operating results and financial condition;

- if we spend significant funds or incur additional debt or other obligations, our ability to obtain financing for working capital or other purposes could decline, and we may be more vulnerable to economic downturns and competitive pressures;

- technological advancement or worse than expected performance of acquired businesses may result in the impairment of intangible assets;

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- we may be unable to realize the anticipated benefits and synergies from acquisitions, such as our recent flow cytometry acquisition, as a result of inherent risks and uncertainties, including difficulties integrating acquired businesses or retaining their key personnel, partners, customers or other key relationships, entering market segments in which we have no or limited experience, and risks that acquired entities may not operate profitably or that acquisitions may not result in improved operating performance;

- we may fail to successfully obtain appropriate regulatory approval or clearance for products under development of our acquired businesses;

- we may be assuming liability for unresolved regulatory risks of our acquired businesses;

- we may fail to successfully manage relationships with customers, distributors and suppliers of our acquired businesses;

- our customers may not accept products of our acquired businesses;

- we may fail to effectively coordinate sales and marketing efforts of our acquired businesses;

- we may fail to combine product offerings and product lines of our acquired businesses quickly and effectively;

- we may fail to effectively enhance acquired technologies and products to develop new products relating to the acquired businesses;

- an acquisition may involve unexpected costs or liabilities, including as a result of pending and future shareholder lawsuits relating to acquisitions or exercise by shareholders of their statutory appraisal rights, or the effects of purchase accounting may be different from our expectations;

- an acquisition may involve significant contingent payments that may adversely affect our future liquidity or capital resources;

- acquisitions and subsequent integration of these companies may disrupt our business and distract our management from other responsibilities; and

- the costs of unsuccessful acquisition efforts may adversely affect our financial performance.

Other risks of integration of acquired businesses include:

- disparate information technology, internal control, financial reporting and record-keeping systems;

- differences in accounting policies, including those requiring judgment or complex estimation processes;

- new partners or customers who may operate on terms and programs different than ours;

- additional employees not familiar with our operations;

- unanticipated additional transaction and integration-related costs;

- our current and prospective customers and suppliers may experience uncertainty associated with an acquisition, including with respect to current or future business relationships with us, and may attempt to negotiate changes in

existing business;

- facilities or operations of acquired businesses in remote locations or potentially foreign jurisdictions and the inherent risks of operating in unfamiliar legal and regulatory environments; and

- new products, including the risk that any underlying intellectual property associated with such products may not have been adequately protected or that such products may infringe on the proprietary rights of others.

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As we continue to expand our business, we may experience problems in scaling our manufacturing operations, or delays or component shortages that could limit the growth of our revenue.

As we continue to expand our manufacturing capabilities in order to meet our growth objectives, we may not be able to produce sufficient quantities of products or maintain consistency between differing lots of consumables. If we encounter difficulties in scaling our manufacturing operations as a result of, among other things, quality control and quality assurance issues and availability of components and raw material supplies, we will likely experience reduced sales of our products, increased repair or re-engineering costs due to product returns and defects and increased expenses due to switching to alternate suppliers, any of which could reduce our revenues and gross margins.

We presently outsource certain aspects of the assembly of our systems to contract manufacturers. Because of a long lead-time to delivery, we are required to place orders for a variety of items well in advance of scheduled production runs. We have increased our flexibility to purchase strategic components within shorter lead times by entering into supply agreements with the suppliers of these components. Although we attempt to match our parts inventory and production capabilities to estimates of marketplace demand, to the extent system orders materially vary from our estimates, we may experience continued constraints in our systems production and delivery capacity, which could adversely impact revenue in a given fiscal period. Should our need for raw materials and components used in production continue to fluctuate, we could incur additional costs associated with either expediting or postponing delivery of those materials. In an effort to control costs we have implemented a lean production system. Managing the change from discrete to continuous flow production requires time and management commitment. Lean initiatives and limitations in our supply chain capabilities may result in parts shortages that delay shipments and cause fluctuations in revenue.

We currently purchase certain key components of our product line from a limited number of outside sources and, in the case of some components, a single source, and these components may only be available through a limited number of providers. We do not have agreements with all of our suppliers. While we currently believe that we will be able to satisfy our forecasted demand for our products, the failure to find alternative suppliers in the event of any type of supply failure at any of our current vendors at reasonably comparable prices could have a material adverse effect on our business, financial condition and results of operations. Additionally, we have entered into supply agreements with most of our suppliers of strategic reagents and component subassemblies to help ensure component availability, and flexible purchasing terms with respect to the purchase of such components. If our suppliers discontinue production of a key component, we will be required to revalidate an affected product and may be required to resubmit a previously cleared product. Our reliance on our suppliers and contract manufacturers exposes us to risks including:

- the possibility that one or more of our suppliers or our assemblers that do not have supply agreements with us could terminate their services at any time without penalty;
- natural disasters such as earthquakes, tsunamis and floods that impact our suppliers;
- the potential obsolescence and/or inability of our suppliers to obtain required components;
- the potential delays and expenses of seeking alternate sources of supply or manufacturing services;
- the inability to qualify alternate sources without impacting performance claims of our products;
- reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternate suppliers or assemblers; and
- increases in prices of raw materials and key components.

Consequently, in the event that supplies of components or work performed by any of our assemblers are delayed or interrupted, our ability to produce and supply our products could be impaired.

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The property rights we rely upon to protect the technologies underlying our products may not be adequate to maintain market exclusivity. Inadequate intellectual property protection could enable third parties to exploit our technologies or use very similar technologies and could reduce our ability to distinguish our products in the market.

Our success depends, in part, on our ability to obtain, protect and enforce patents on our technologies and products and to protect our trade secrets, including the intellectual property of entities we may acquire. Any patents we own may not afford full protection for our technologies and products. Other parties may challenge the validity of our patents and, as a result, our patents could be narrowed or invalidated in administrative or judicial proceedings. In addition, our current and future patent applications may not result in the issuance of patents in the United States or foreign countries. Competitors may develop products that are not covered by our patents. Furthermore, there is a substantial backlog of patent applications at the U.S. Patent and Trademark Office and certain patent offices in foreign jurisdictions, and the approval or rejection of patent applications may take several years.

We currently own 728 issued patents worldwide, including 243 issued patents in the United States. Other countries in which we have issued patents directed to various aspects and applications of our products and technologies include France, Germany, the United Kingdom, Australia, Japan, Netherlands, Canada, Hong Kong and China, amongst others. In addition, our patent portfolio includes 160 pending patent applications in the United States and other foreign jurisdictions. We also have patents covering key aspects of MultiCode technology, xTAG technology, and nanoparticle technology, utilized in our assays as well as our ARIES® and VERIGENE Systems, NxTAG technology imaging flow cytometry technology and capillary flow cytometry technology.

We seek to require employees, consultants, strategic partners and other third parties to execute confidentiality agreements. Our employees and third-party consultants also sign agreements requiring that they assign to us their interests in inventions and original expressions and any corresponding patents and copyrights arising from their work for us. In addition, we have implemented a patent process to file patent applications on our key technologies. However, we cannot guarantee that these agreements or this patent process will provide us with adequate protection against improper use of our intellectual property or disclosure of confidential information. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisers have prior employment or consulting relationships. Further, others may independently develop substantially equivalent proprietary technologies, techniques and products or counterfeit versions of our products or otherwise gain access to our trade secrets. Our failure to protect our proprietary information and techniques may inhibit or limit our ability to distinguish our products in the market.

In order to protect or enforce our patent rights, we may have to initiate legal proceedings against third parties, such as infringement suits or interference proceedings. These legal proceedings could be expensive, take significant time and/or divert management’s attention from other business concerns. These proceedings may cause us to lose the benefit of some of our intellectual property rights, the loss of which may inhibit or preclude our ability to distinguish our products in the market. These proceedings also may provoke these third parties to assert claims against us. Moreover, a series of decisions from the Supreme Court of the United States have arguably weakened United States patent rights, including the Impression Products v. Lexmark case, which expands the scope of the patent exhaustion doctrine to sales of patented products outside of the United States and limits a patent holder’s ability to enforce post-sale restrictions under patent law. The patent position of companies like ours generally is highly uncertain, involves complex legal and factual questions and has recently been the subject of much litigation. No consistent policy has emerged from the U.S. Patent and Trademark Office or the courts regarding the breadth of claims allowed or the degree of protection afforded under patents like ours.

If our current products and our products under development do not become widely used in the life sciences and clinical diagnostics industries, we may not be able to maintain or increase profitability.

Life sciences and clinical diagnostic service provider companies have historically conducted biological tests using a variety of technologies, including bead-based analysis. The commercial success of our products depends upon their widespread adoption as methods to perform assays. In order to be successful, we must convince potential partners and customers to utilize our systems instead of other competing products. Market acceptance depends on many factors, including our ability to:

- timely and successfully launch our products under development;
- manage trends relating to, or the introduction or existence of, competing products or technologies that may be more effective, cheaper or easier to use than our products and technologies;
- operate in a highly competitive marketplace, including in the presence of competing products sold by companies with longer operating histories, more recognizable names and more established distribution networks;

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- convince prospective strategic partners and customers that our products are an attractive alternative to others for research, clinical, biomedical and genetic testing and analysis;
- encourage these partners to develop and market products using our technologies;
- manufacture products in sufficient quantities with acceptable quality and at an acceptable cost;
- obtain and maintain sufficient pricing and royalties from partners on such Luminex products; and
- place and service sufficient quantities of our products at the level of service required in the life science and clinical diagnostics market segments.

Because of these and other factors, our products may not gain or sustain sufficient market acceptance to maintain or increase profitability. Additionally, we may have to write off excess or obsolete inventory if sales of our products are not consistent with our expectations or if the demand for our products changes.

In the molecular diagnostics sector, we must recognize significant market uptake in order to gain operational efficiencies and reduce costs based on increased volume.

Currently, a limited number of direct customers and strategic partners account for a significant portion of our revenue and the loss of any one of these or their inability to perform to expectations could have a material adverse effect on our business, financial condition, and results of operations. Our success depends significantly on the establishment and maintenance of successful relationships with our direct customers and strategic partners.

LabCorp, Thermo Fisher Scientific Inc., and Bio-Rad Laboratories, Inc., accounted for 35% of total revenue (15%, 14% and 6%, respectively) in the twelve months ended December 31, 2018. For comparative purposes, these same three companies accounted for 41% of total revenue (20%, 15% and 6%, respectively) in the twelve months ended December 31, 2017 and 40% of total revenue (20%, 13% and 7%, respectively) in the twelve months ended December 31, 2016. No other customer accounted for more than 5% of total revenue during the twelve months ended December 31, 2018. In total, for the years ended December 31, 2018 and 2017, our top five customers accounted for 42% and 48%, respectively, of our total revenue. The loss of any of our significant direct customers, strategic partners, or the loss of a material portion of the sales to these customers or partners could have a material adverse effect on our growth and future results of operations.

LabCorp elected to develop the next iteration of one of its women's health products with another party. We previously negotiated significant minimum requirements of women's health purchases from LabCorp, pursuant to which LabCorp committed to acquire no less than $63.1 million of our women's health products from January 1, 2017 through June 30, 2018. During the quarter ended June 30, 2018, LabCorp met its purchase requirements under that agreement and indicated it will not make further purchases from us of the women's health products covered by such agreement. However, based on an extension agreement entered into in the third quarter of 2017, the Company will continue to sell its CF products to LabCorp through at least the end of 2019. The loss of the women's health LabCorp business, and the anticipated future loss of other products traditionally sold to LabCorp (which we expect to occur with products other than CF, as discussed above), could have a material adverse effect on our growth and future results of operations.

During 2018, LabCorp represented total revenue of $47.3 million. That revenue was categorized as follows: women's health - $23.2 million; CF related - $12.4 million; and all other ancillary products - $11.7 million. As noted above, LabCorp met its purchase commitment for women's health products and will no longer be placing material orders for the women's health portfolio. The remainder of the women's health products purchased by LabCorp have also been transitioned to another party. LabCorp orders for our CF products are expected to continue through at least the end of

2019. Orders by LabCorp for other ancillary products are at risk for a potential material reduction in 2019.

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Delays in implementation, delays in obtaining regulatory approval, changes in strategy, or the financial difficulty of our strategic partners for any reason could have a material adverse effect on our business, financial condition, and results of operations.

Our ability to enter into agreements with additional strategic partners depends in part on convincing them that our products can help achieve and accelerate their goals or efforts. We expend substantial funds and management efforts with no assurance that any additional strategic relationships will result. We cannot guarantee that we will be able to negotiate additional strategic agreements in the future on acceptable terms, if at all, or that current or future strategic partners will not pursue or develop alternative technologies either on their own or in collaboration with others. Some of the companies we are targeting as strategic partners offer products competitive with our xMAP Technology, which may hinder or prevent strategic relationships. Delays in implementation of new products by our strategic partners, changes in their strategy, financial difficulties they experience, or delays in obtaining or their inability to obtain regulatory approval for their products could negatively affect our business. Termination of strategic relationships, the failure to enter into a sufficient number of additional strategic relationships on favorable terms, or disputes with our partners could reduce sales of our products, lower margins on our products and limit the market demand for and acceptance of our products.

As we pursue the development and registration of products, regulation by governmental authorities in the United States and other countries will be a significant factor in the development, testing, production, and marketing of such products. Products that we develop in the molecular diagnostic markets will be regulated as medical devices by the FDA and other global governmental authorities and may require receipt of clearance following a pre-market notification process prior to marketing. Obtaining the requisite regulatory approvals can be expensive and may involve considerable delay. Changes to the current regulatory framework, including additional or new regulations, could arise at any time during the development or marketing of our products, which may negatively affect our ability to obtain regulatory approval of our products.

If the quality of our products does not meet our customers' expectations, our reputation could suffer and ultimately our sales and operating earnings could be negatively impacted.

In the course of conducting our business, we must adequately address quality issues associated with our products and services, including defects in our engineering, design and manufacturing processes, as well as defects in third-party components included in our products. Because our instruments and consumables are highly complex, the occurrence of defects may increase as we continue to introduce new products and services and as we rapidly scale up manufacturing to meet increased demand for our products and services. Although we have established internal procedures to minimize risks that may arise from product quality issues, there can be no assurance that we will be able to eliminate or mitigate occurrences of these issues and associated liabilities. In addition, identifying the root cause of quality issues, particularly those affecting reagents and third-party components, may be difficult, which increases the time needed to address quality issues as they arise and increases the risk that similar problems could recur. Finding solutions to quality issues can be expensive and we may incur significant costs or lost revenue in connection with, for example, shipment holds, product recalls and warranty or other service obligations. In addition, quality issues can impair our relationships with new or existing customers and adversely affect our brand image, and our reputation as a producer of high quality products could suffer, which could adversely affect our business, financial condition or results of operations.

Uncertain economic conditions and outlook may adversely impact our business, results of operations, financial condition, or liquidity.

Global economic conditions could adversely affect our results of operations. The credit markets and the financial services industry continue to experience volatility, both domestically and internationally. These conditions not only

limit our access to capital but also make it extremely difficult for our customers, our vendors and us to accurately forecast and plan future business activities, and they could cause U.S. and foreign businesses and consumers to slow spending on our products and services, which would delay and lengthen sales cycles. Some of our customers rely on government research grants to fund technology purchases. If negative trends in the economy affect the government's allocation of funds to research, there may be less grant funding available for certain of our customers to purchase technologies like those Luminex sells. Certain of our partners and their and our customers may face challenges gaining timely access to sufficient credit or may otherwise be faced with budget constraints, which could result in decreased purchases of, or development of products based on, our products or in an impairment of their ability to make timely payments to us. If our partners and our customers do not make timely payments to us, we may be required to assume greater credit risk relating to those customers, increase our allowance for doubtful accounts and our days sales outstanding would be negatively impacted. Although we maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments, and such losses have historically been within our expectations and the provisions established, we may not continue to experience the same loss rates that we have in the past given the current condition of the worldwide economy. Additionally, these economic conditions and market turbulence may also impact our suppliers causing them to be unable to supply sufficient quantities of customized components in a timely manner, thereby impairing our ability to manufacture on schedule and at commercially reasonable costs.

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If our direct selling efforts for our products are less successful than anticipated, our business expansion plans could suffer and our ability to generate revenues could be diminished.

If our direct sales force is not successful, or additions to our sales team fail to gain traction among our customers, we may not be able to increase market awareness and sales of our products, or to maintain historical sales levels. If we fail to establish our systems in the marketplace, it could have a negative effect on our ability to sell subsequent systems and hinder the planned expansion of our business.

The commercial launch of the ARIES® System was the first Luminex system launch that was not channeled through a partner. The successful execution of our product launch and adoption by our direct customers has been and will continue to be critical to establishing an installed base of satisfied customers. To the extent that these customers do not continue to adopt the menu of ARIES® assays that have been a significant focus of our research and development efforts over the last four years, there is a significant risk that our investment in these assays may not pay off. Additionally, we have made a significant investment in our customer service, support and direct sales force to support the launches of ARIES® Systems. Our ability to service, support and sell the ARIES® and VERIGENE Systems directly, and not through a partner, may also fail to meet ongoing market expectations, which could have a material adverse effect on our business, financial condition and results of operations.

If third-party payors continue to increasingly restrict payments for healthcare expenses or fail to adequately pay for multi-analyte testing, we may experience reduced sales, which would hurt our business and our business prospects.

Third-party payors, government-sponsored healthcare programs (e.g., Medicare, Medicaid and Tricare), health maintenance organizations, preferred provider organizations and other private or commercial insurers are continually seeking to reduce healthcare expenses. Payors are challenging the utilization of, and prices charged for, medical services, including clinical diagnostic tests. The federal government has implemented cost-cutting strategies for government-sponsored healthcare programs, including coverage limitations and reimbursement rate reductions required by the Affordable Care Act. In 2016, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that significantly revised the reimbursement methodology under the Clinical Diagnostic Laboratory Test Payment System required by the Protecting Access to Medicare Act. Beginning January 1, 2018, payment rates for most tests included in the Clinical Laboratory Fee Schedule are based on commercial insurance rates, which certain laboratories are required to report. The revised reimbursement methodology resulted in reduced rates in 2018, and further reductions will be phased in through 2022. We expect reimbursement rates to trend down over time. Coverage and reimbursement from commercial payors may also reflect these reductions.

Further cost containment initiatives by governmental or educational entities or programs may reduce funding for genetic research and development activities and slow the growth of the genetic testing market. Lack of adequate coverage or reimbursement for our products could affect consumer demand, reducing volumes or adding additional cost pressures, resulting in lowered prices for our products. Reduced sales or margins by us, or our direct customers, and strategic partners, would adversely affect our business, profitability and business prospects. In addition, failure to secure appropriate reimbursement in foreign jurisdictions could severely limit our ability to expand sales within these markets.

Our success depends partly on our ability to operate without infringing on or misappropriating the proprietary rights of others.

We have been (and from time to time we may be) notified that third parties consider their patents or other intellectual property relevant to our products. We may be sued for infringing the intellectual property rights of others, including claims with respect to intellectual property of entities we may acquire. In addition, we may find it necessary, if

threatened, to initiate a lawsuit seeking a declaration from a court that we do not infringe on the proprietary rights of others or that their rights are invalid or unenforceable. Intellectual property litigation is costly, and, even if we prevail, the cost of such litigation could affect our profitability. Furthermore, litigation is time-consuming and could divert management's attention and resources away from our business. If we do not prevail in any litigation, we may have to pay damages and could be required to stop the infringing activity or obtain a license. Any required license may not be available to us on acceptable terms, if at all. Moreover, some licenses may be nonexclusive, and therefore our competitors may have access to the same technology licensed to us. If we fail to obtain a required license or are unable to design around a patent, we may be unable to sell some of our products, which could have a material adverse effect on our business, financial condition and results of operations.

We require collaboration with other organizations in obtaining relevant biomarkers, access to oligonucleotides and enzymes that are patented or controlled by others. If we cannot continue to obtain these items or identify freedom to operate opportunities, our business, financial condition and results of operations could be negatively affected.

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Security breaches, including with respect to cybersecurity, and other disruptions could compromise our information, products, and services and expose us to liability and harm our reputation and business.

In the ordinary course of our business we collect and store sensitive data, including intellectual property, personal information, our proprietary business information and that of our customers, suppliers and business partners and personally identifiable information of our customers and employees in our data centers and on our networks. The secure maintenance and transmission of this information is critical to our operations and business strategy. We rely on commercially available systems, software, tools and domestically available monitoring to provide security for processing, transmitting and storing this sensitive data. As a participant in the molecular diagnostic market, we may face cyber-attacks that attempt to penetrate our network security, including our data centers, sabotage or otherwise disable our research, products and services, including instruments at our customers' sites, which may include personally identifiable information, or cause interruptions of our internal systems.

If successful, hackers may misappropriate personal or confidential business information. In addition, an associate, contractor or other third party with whom we do business may attempt to circumvent our security measures in order to obtain such information, and may purposefully or inadvertently cause a breach involving such information due to items such as business email compromise. While we continue to implement additional protective measures to reduce the risk of and detect cyber incidents, cyber-attacks are becoming more sophisticated and frequent, and the techniques used in such attacks change rapidly. Despite our cybersecurity measures (including employee and third-party training, monitoring of networks and systems and maintenance of backup and protective systems) which are continuously reviewed and upgraded, the Company's information technology networks and infrastructure may still be vulnerable to damage, disruptions or shutdowns due to attack by hackers or breaches, employee error or malfeasance, power outages, computer viruses, telecommunication or utility failures, systems failures, natural disasters or other catastrophic events. Any such compromise of our, or our third-party IT service providers' data security and any access, public disclosure or loss of personal or confidential business information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, monetary losses, disrupt our operations, damage our reputation and customers' willingness to transact business with us and subject us to additional costs and liabilities, any of which could adversely affect our business.

We expect our operating results to continue to fluctuate from quarter to quarter.

The sale of our instrumentation and assays typically involves a significant technical evaluation and commitment of capital by us, our partners and end users. Accordingly, the sales cycle associated with our products is typically lengthy and subject to a number of significant risks, much of which is beyond our control, including partners' budgetary constraints, inventory management practices, regulatory approval and internal acceptance reviews. As a result of this lengthy and unpredictable sales cycle, our operating results have historically fluctuated significantly from quarter to quarter. We expect this trend to continue for the foreseeable future.

The vast majority of our system sales are made to our strategic partners. Our partners typically purchase instruments in three phases during their commercialization cycle: first, instruments necessary to support internal assay development; second, instruments for sales force demonstrations; and finally, instruments for resale to their customers. As a result, most of our system placements are highly dependent on the continued commercial success of our strategic partners and can fluctuate from quarter to quarter as our strategic partners move from phase to phase. We expect this trend to continue for the foreseeable future.

Our assays are sometimes sold to large customers. The ordering and consumption patterns of these customers can fluctuate, affecting the timing of shipments and revenue recognition. In addition, certain products assist in the diagnosis of illnesses that are seasonal, and customer orders can fluctuate for this reason. The loss of any of these customers (including LabCorp's decision to move to an alternative vendor for women's health products in 2018) has

had and is expected to continue to have a material adverse effect or our business, financial condition and results of operations.

The seasonality of some of our assay offerings results in quarter to quarter fluctuations in the percentage of our quarterly revenues derived from our highest margin items (i.e., consumables, royalties and assays), as customers make infrequent bulk purchases of $100,000 or more to address this demand. Our gross margin percentage is highly dependent upon the mix of revenue components each quarter. These fluctuations contribute to the variability and lack of predictability of both gross margin percentage and total gross profit from quarter to quarter. We expect this trend to continue for the foreseeable future.

Due to the early stage of the market for molecular tests, projected growth scenarios for our assays are highly volatile and are based on a number of underlying assumptions that may or may not prove to be valid, including our ability to be successful with our direct assay sales strategy.

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Our success depends on our ability to service and support our products directly or in collaboration with our strategic partners.

To the extent that we or our strategic partners fail to maintain a high quality level of service and support for xMAP products, there is a risk that the perceived quality of our xMAP products will be diminished in the marketplace. Likewise, we may fail to provide the level, quantity or quality of service expected by the marketplace. This could result in slower adoption rates and lower than anticipated utilization of xMAP products, which could have a material adverse effect on our business, financial condition and results of operations.

Our success depends on our ability to attract and retain our management and staff.

We depend on the principal members of our management and scientific staff, including our chief executive officer, Nachum Shamir, and our operations, marketing, research and development, technical support, technical service and sales staff. The loss of services of key members of management could delay or reduce our product development, marketing and sales and technical support efforts. In addition, recruiting and retaining qualified scientific and other personnel to perform research and development, technical support, technical service and marketing and sales work will be critical to our success. There is a shortage in our industry of qualified management and scientific personnel, and competition for these individuals is intense. There can be no assurance that we will be able to retain existing and attract additional personnel necessary to achieve our business objectives.

In most of our strategic partnerships we have granted non-exclusive rights with respect to commercialization of our products and technologies.

We expect that a significant portion of our future revenues will come from sales of our systems and the development and sale of kits utilizing our xMAP consumables by our strategic partners and from use of our xMAP products by our strategic partners in performing services offered to third parties. We believe that our strategic partners will have economic incentives to develop and market these products, but we cannot accurately predict future sales and royalty revenues because some of our existing strategic partner agreements do not include minimum purchase requirements or minimum royalty commitments. Some of our existing strategic partner agreements contain minimum purchase requirements for certain years, but unless renegotiated, these minimum purchase requirements could and do expire. In addition, we have no control with respect to our strategic partners' sales personnel and how they prioritize products based on xMAP technology, nor can we control the timing of the development or release of products by our strategic partners. The amount of these revenues depends on a variety of factors that are outside our control, including the amount and timing of resources that current and future strategic partners devote to develop and market products incorporating our technology. Furthermore, the development and marketing of certain kits will require our strategic partners to obtain governmental approvals, which could delay or prevent their commercialization efforts. If our current or future strategic partners do not successfully develop and market products based on our technology and obtain necessary government approvals, our revenues from product sales and royalties could be significantly reduced.

Our products are subject to extensive regulation by the FDA, including the requirement to obtain premarket approval and the requirement to report adverse events and violations of the FDC Act that could present significant risk of injury to patients. Even though we have received FDA approval of our PMA applications and 510(k) clearances to commercially market our products, we will continue to be subject to extensive FDA regulatory oversight.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In general, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval

application, or PMA unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other pre-amendment, 510(k)-exempt, 510(k) cleared products, or PMA-approved products that have subsequently been down-classified. If the FDA determines that the device is not “substantially equivalent” to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the de novo process. Pursuant to amendments to the statute in 2012, a manufacturer can also submit a petition for a direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

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High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. Currently, all of our products requiring FDA clearance or approval are class II and have been cleared through the 510(k) process.

Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products internationally, we may be subject to rigorous international regulation in the future. In these circumstances, we would rely significantly on our foreign independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

Modifications to our marketed products may require new 510(k) or de novo clearances or PMA approvals, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

Modifications to our products may require new regulatory approvals or clearances, including 510(k) or de novo clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. For example, a manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

For those products sold in the European Union we must notify our E.U. Notified Body if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

If our products contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device were to recur. As required per the FDA Code of Federal Regulations (21 CFR) Part 803, we have established procedures and processes for documentation and evaluation of all complaints relative to reporting requirements. As with all device

manufacturers, we have 30 days from "becoming aware" of an incident to submit to FDA a MDR for an event that reasonably suggests that a device has or may have caused or contributed to the incident, or five work days for an event designated by FDA or an event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

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If we or our suppliers fail to comply with ongoing FDA or foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance, and the manufacturing processes, reporting requirements, post-market clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our strategic partners who manufacture medical devices are required to comply with the Quality System Regulations ("QSR"). The QSR covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we, or our strategic partners, fail to adhere to QSR requirements in the United States or experience delays in obtaining necessary regulatory approvals or clearances, this could delay production of our products and lead to fines, difficulties in obtaining regulatory approvals or clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

In addition, the FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. Any failure to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspection observations or product safety issues, could result in any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing or delaying our requests for regulatory approvals or clearances of new products or modified products;
- withdrawing PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in a failure to produce our products on a timely basis and in the required quantities, if at all.

Our products and operations are required to comply with standards set by foreign regulatory bodies, and those standards, types of evaluation and scope of review differ among foreign regulatory bodies. If we fail to comply with any of these standards adequately or if changes to our manufacturing or supply practices require additional regulatory approval, a foreign regulatory body may take adverse actions or cause delays within their jurisdiction similar to those within the power of the FDA. Any such action or circumstance may harm our reputation and business, and could have an adverse effect on our business, results of operations and financial condition.

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Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

U.S. legislative, FDA or global regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Moreover, leadership, personnel and structural changes within the FDA as well as recent and future federal election outcomes could result in significant legislative and regulatory reforms impacting the FDA’s regulation of our products. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

In addition, on May 25, 2017, the new Medical Devices Regulation (2017/745 or “MDR”) entered into force. Following its entry into application on May 26, 2020, the MDR will introduce substantial changes to the obligations with which medical device manufacturers must comply in the EU. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. Specifically, the EU Medical Devices Regulation repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the European Economic Area (“EEA”) Member States, the regulations would be directly applicable, i.e., without the need for adoption of EEA member state laws implementing them, in all EEA Member States and are intended to eliminate current differences in regulation of medical devices among EEA Member States. The EU MDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices to ensure a high level of safety and health while supporting innovation. The MDR will however only become applicable in three years after publication (in May 2020). Once applicable, the new regulations will among

other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices which may have to undergo an additional check by experts before they are placed on the market.

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Once applicable, the MDR may impose increased compliance obligations for us to access the EU market.

In order to continue to sell our products in Europe, we must maintain our CE marks and continue to comply with certain EU directives and, in the future with the MDR. Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our Notified Body, which could impair our ability to market products in the EEA in the future. Any changes to the membership of the European Union, such as the departure of the United Kingdom (Brexit), may impact the regulatory requirements for the impacted countries and impair our business operations and our ability to market products in such countries.

If the governmental laws and regulations change in ways that we do not anticipate or if we fail to comply with existing laws and regulations that affect our business, we could be subject to enforcement actions, injunctions and civil and criminal penalties or otherwise be subject to increased costs that could delay or prevent marketing of our products.

Medical device laws and regulations are in effect within the United States and also in many countries outside the United States. These range from comprehensive device clearance requirements for some or all of our medical device products to requests for product data or certifications regarding the hazardous material content of our products. As a device manufacturer, we are required to report annually to the CMS any payments or transfers of value we have made to physicians and teaching hospitals and any physician ownership or investment interest in the company. As part of the European Council Directive 2002/96 of February 13, 2003, we are expected to comply with certain requirements regarding the collection, recycling and labeling of our products containing electronic devices in each of the EU member states where our regulated products are distributed. While we are taking steps to comply with the requirements of WEEE, we cannot be certain that we will comply with the national stage implementation of WEEE in all member states. We continue to evaluate the necessary steps for compliance with regulations as they are enacted. These regulations include, for example, the Registration, Evaluation, Authorization and Restriction of Chemical substances, the RoHS Directive and the WEEE Directive enacted in the European Union, which regulate the use of certain hazardous substances in, and require the collection, reuse and recycling of waste from, certain products we manufacture. This and similar legislation that has been or is in the process of being enacted in various countries may require us to re-design our products to ensure compliance with the applicable standards. These redesigns may impact the performance of our products, add greater testing lead-times for product introductions or have other similar effects. We believe we comply with all such legislation where our products are sold and we will continue to monitor these laws and the regulations being adopted under them to determine our responsibilities. In addition, the State of California adopted the Electronic Waste Recycling Act, effective January 1, 2007, which requires the California Department of Toxic Substances Control to adopt regulations to prohibit the sale of electronic devices in California if they are also prohibited from sale in the EU under the RoHS Directive because they contain certain heavy metals. The number and scope of these requirements are increasing and we will likely become subject to similar laws in other jurisdictions. Failure to comply with applicable federal, state and foreign medical device laws and regulations may harm our business, financial condition and results of operations. We are also subject to a variety of other laws and regulations relating to, among other things, environmental protection and workplace health and safety.

Our strategic partners and customers expect our organization to operate on an established quality management system compliant with FDA Quality System Regulations and industry standards, the In Vitro Diagnostic Directive 98/79/EC of 27 October 1998 (Directive) as implemented nationally in the EU member states and industry standards, such as ISO 9000. We became ISO 9001:2000 certified in March 2002 and self-declared our Luminex 100/200, FLEXMAP 3D and MAGPIX instruments to the Directive. Our devices are in conformity with Article 1, Article 9, Annex I (Essential Requirements), Annex III and the additional provisions of the Directive as of December 7, 2003. Subsequent audits are carried out annually to ensure we maintain our system in substantial compliance with ISO and other applicable regulations and industry standards. We became ISO 13485:2003 and Canadian Medical Devices

Conformity Assessment System (CMDCAS) certified in July 2005. Failure to maintain compliance with FDA, CMDCAS and EU regulations and other medical device laws, or to obtain applicable registrations where required, could reduce our competitive advantage in the markets in which we compete and also decrease satisfaction and confidence levels with our partners.

Our reliance on strategic partnerships makes forecasting difficult.

As a result of our reliance on our strategic relationships, it can be difficult to accurately forecast future operating results. Estimating the timing and amount of sales of our products is particularly difficult for the following reasons (among others):

- we do not control the timing or extent of product development, marketing or sale of our products by our strategic partners;

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- we do not control the incentives provided by our strategic partners and distributors to their sales personnel;

- we utilize a limited number of geographically focused distributors for a portion of our sales, including sales of several of our key assays, and the loss of or nonperformance by these distributors could harm our revenues in the territories serviced by these distributors;

- a significant number of our strategic partners intend to produce clinical diagnostic applications that may need to be approved by the FDA or other regulatory bodies in jurisdictions outside of the United States;

- certain strategic partners may have unique requirements for their applications and systems. Assisting the various strategic partners may strain our research and development and manufacturing resources. To the extent that we are not able to timely assist our strategic partners, the commercialization of their products will likely be delayed;

- certain strategic partners may fail to deliver products that satisfy market requirements, or such products may fail to perform properly;

- we have limited access to partner and distributor confidential corporate information. A sudden unexpected change in ownership or strategy or other material event due to information of which we are not currently aware could adversely impact partner purchases of our products; and

- partners tend to order in bulk prior to the production of new lots of their products and prior to major product development initiatives. The frequency of these bulk purchases is difficult to predict and may cause large fluctuations in microsphere sales quarter to quarter.

The capital spending policies of our customers have a significant effect on the demand for our products.

Our customers include clinical diagnostic, pharmaceutical, biotechnological, research institutions, chemical and industrial companies, and the capital spending policies of these companies can have a significant effect on the demand for our products. These policies are based on a wide variety of factors, including general or local economic conditions, governmental regulation or price controls, resources available for purchasing research equipment, government funding, grants, spending priorities among various types of analytical equipment and policies regarding capital expenditures during recessionary periods. Any decrease in capital spending by life sciences companies could cause our revenues to decline. As a result, we are subject to significant volatility in revenue. Therefore, our operating results can be materially affected (negatively and positively) by the spending policies and priorities of our customers.

If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the testing, production, marketing and sale of biotechnological, human diagnostic and therapeutic products. Although we believe that we are reasonably insured against these risks and we generally have limited indemnity protections in our supplier agreements, there can be no assurance that we will be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. A product liability claim in excess of our insurance coverage or a claim that is outside of or exceeds our indemnity protections in our supplier agreements or a recall of one of our products would have to be paid out of our cash reserves.

If we become subject to claims relating to improper handling, storage or disposal of hazardous materials, we could incur significant cost and time to comply.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials, including biological hazardous materials. We are subject to foreign, federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. We may incur significant costs complying with both existing and future environmental laws and regulations. In particular, we are subject to regulation by the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA), and to regulation under the Toxic Substances Control Act and the Resource Conservation and Recovery Act in the United States. OSHA or the EPA may adopt regulations that may affect our research and development programs. We are unable to predict whether any agency will adopt any regulations that would have a material adverse effect on our operations.

The risk of accidental contamination or injury from hazardous materials cannot be eliminated completely. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our workers' compensation insurance. We may not be able to maintain insurance on acceptable terms, if at all.

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We may incur impairment charges on our goodwill and intangible assets which would reduce our earnings.

We are subject to Accounting Standards Codification (ASC) 350 “Goodwill and Other” (ASC 350) which requires that goodwill and other intangible assets that have an indefinite life be tested at least annually for impairment. Goodwill and other intangible assets with indefinite lives must also be tested for impairment between the annual tests if a triggering event occurs that would likely reduce the fair value of the asset below its carrying amount. As of December 31, 2018, goodwill and other intangible assets with indefinite lives represented approximately 43% of our total assets. In the future, if we determine that there has been impairment, our financial results for the relevant period would be reduced by the amount of the impairment, net of tax effects, if any.

If a catastrophe strikes our manufacturing or warehousing facilities, we may be unable to manufacture or distribute our products for a substantial amount of time and we may experience inventory shortfalls, which would cause us to experience lost revenues.

Our manufacturing facilities are located in Austin, Madison, Northbrook, Toronto and Seattle. Although we have business interruption insurance, our facilities and some pieces of manufacturing equipment are difficult to replace and could require substantial replacement lead time. Various types of disasters, including tornadoes, fires, floods and acts of terrorism, may affect our manufacturing facilities. In the event our existing manufacturing facilities or equipment are affected by man-made or natural disasters, we may be unable to manufacture products for sale or meet customer demands or sales projections. If our manufacturing operations were curtailed or ceased, it would seriously harm our business.

Our success depends on building and sustaining our technology infrastructure.

We are increasingly dependent on information technology to enable us to improve the effectiveness of our operations and to maintain financial accuracy and efficiency. If we do not allocate and effectively manage the resources necessary to build, implement and sustain the proper technology infrastructure, we could be subject to transaction errors, the inability to properly support and service our customers, processing inefficiencies, loss of customers, business disruptions or loss of or damage to intellectual property through security breach or cyber-attack, each of which could materially and adversely affect our business.

Our operations in foreign countries expose us to certain risks inherent in doing business internationally, which may adversely affect our business, financial condition, and results of operations.

We expect that revenue from U.S. sales will continue to represent the majority of our total revenue, but our future profitability will depend in part on our ability to grow and ultimately maintain our product sales in foreign markets, particularly in Asia and Europe. In fiscal 2018, approximately 17% of our revenue was derived from sales to non-U.S. customers, with approximately 7% of revenue from sales to customers in Europe. As such, a significant slowdown in these foreign economies or lower investments in new infrastructure could have a negative impact on our sales. We also purchase a portion of the materials included in our products from overseas sources. As a result of acquisitions and organic growth, we have operations and manufacturing facilities in foreign countries that expose us to certain risks. For example, fluctuations in exchange rates may affect our revenues, expenses and results of operations, as well as the value of our assets and liabilities as reflected in our financial statements. We are also subject to other types of risks, including the following:

- changes in or interpretations of foreign law that may adversely affect our ability to sell our products, perform services or repatriate profits to the United States;

- tariffs, customs and other barriers to importing/exporting materials and products in a cost effective and timely manner;
- hyperinflation or economic or political instability in foreign countries;
- imposition of limitations on or increase of withholding and other taxes on remittances and other payments by foreign subsidiaries;
- conducting business in places where business practices and customs are unfamiliar and unknown;
- difficulties in staffing and managing international operations;
- the burden of complying with complex and changing foreign regulatory requirements;

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- difficulties in accounts receivable collections;
- the imposition of restrictive trade policies, including export restrictions;
- worldwide political conditions;
- the imposition of inconsistent laws or regulations;
- reduced protection of intellectual property rights and trade secrets in some foreign countries;
- the imposition or increase of investment requirements and other restrictions by foreign governments;
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;
- uncertainties relating to foreign laws, including labor laws, and legal proceedings;
- the burden of complying with foreign and international laws and treaties;
- significant currency fluctuations;
- the burden of complying with and changes in international taxation policies;
- the burden of complying with a variety of U.S. laws, including the Foreign Corrupt Practices Act;
- the burden of complying with U.S. export control regulations and policies that restrict our ability to communicate with non-U.S. employees and to supply foreign affiliates, partners and customers; and
- the burden of complying with applicable international laws governing privacy and data security, such as the new European Union General Data Protection Regulation.

Our international sales and purchases are subject to numerous U.S. and foreign laws and regulations, including, without limitation, tariffs, trade barriers, regulations relating to import-export control, technology transfer restrictions, the International Traffic in Arms Regulation promulgated under the Arms Export Control Act, the Foreign Corrupt Practices Act and the anti-boycott provisions of the U.S. Export Administration Act. If we fail to comply with these laws and regulations, we could be liable for administrative, civil or criminal liabilities, and in the extreme case, we could be suspended or debarred from government contracts or have our export privileges suspended, which could have a material adverse effect on our business.

International sales and purchases are also subject to a variety of other risks, including risks arising from currency fluctuations, collection issues and taxes. Our international sales are subject to variability as our selling prices become less competitive in countries with currencies that are declining in value against the U.S. dollar and more competitive in countries with currencies that are increasing in value against the U.S. dollar. In addition, our international purchases can become more expensive if the U.S. dollar weakens against the foreign currencies in which we are billed.

We have not entered into any foreign currency derivative financial instruments; however, we may choose to do so in the future in an effort to manage or hedge our foreign exchange rate risk.

There can be no assurance that we will continue to pay dividends.

In February 2017, the Board of Directors initiated a cash dividend program under which the Company will pay a regular quarterly cash dividend. The declaration, amount and timing of such dividends are subject to capital availability and determinations by our Board of Directors that cash dividends are in the best interest of our stockholders and are in compliance with all respective laws and our agreements applicable to the declaration and payment of cash dividends. Our continuing ability to pay dividends will depend upon, among other factors, our cash balances and potential future capital requirements for strategic transactions, including acquisitions, debt service requirements, results of operations, financial condition and other factors beyond our control that our Board of Directors may deem relevant. A reduction in or elimination of our dividend payments, or our dividend program could have a negative effect on our stock price.

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We rely on the innovation and resources of larger industry participants and public programs in our partnership business to advance genomic research and educate physicians/clinicians on genetic diagnostics.

The linkages between genetic anomalies that our products detect and the underlying disease states are not always fully medically correlated. Additionally, the availability of correlated genetic markers is dependent on significant investment in genomic research, often funded through public programs, for which there are no assurances of ongoing support. Should any government limit patent rights to specific genetic materials, private investment in this area could also be significantly curtailed. In addition, the adoption of genetic diagnostics is dependent to a great extent on the education and training of physicians and clinicians. We do not have the resources to undertake such training, and are relying on larger industry participants and professional medical colleges to establish, communicate and educate physicians and clinicians on best practices related to genetic diagnostics.

We are subject to evolving legislative, regulatory, judicial and ethical standards on use of technology and biotechnology.

The adoption of genetic testing is occurring within the broader context of a myriad of decisions related to genetic patenting and genotyping. Issues associated with health insurance, data access, intellectual property protection, national and international legislative and regulatory initiatives and other variables may have a significant impact on the widespread adoption of genetic testing or on specific segments or tests within the genetic testing market, which could in turn impact our business.

Our effective tax rate may fluctuate and we may incur obligations in tax jurisdictions in excess of amounts that have been accrued.

We are subject to income taxes in the United States and various foreign jurisdictions. Our effective tax rate may be lower or higher than experienced in the past due to numerous factors, including a change in the mix of our profitability from country to country, the establishment or release of valuation allowances against our deferred tax assets, and changes in tax laws. In addition, we have recorded gross unrecognized tax benefits in our financial statements that, if recognized, would impact our effective tax rate. We are subject to tax audits in various jurisdictions, including the United States, and tax authorities may disagree with certain positions we have taken and assess additional taxes. There can be no assurance that we will accurately predict the outcomes of these audits, and the actual outcomes could have a material impact on our net income or financial condition. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have an adverse effect on our business and results of operations. The recognition of deferred tax assets is reduced by a valuation allowance if it is more likely than not that the tax benefits will not be realized. We regularly review our deferred tax assets for recoverability and establish a valuation allowance based on historical income, projected future income, the expected timing of the reversals of existing temporary differences, and the implementation of tax-planning strategies.

Changes in tax laws or tax rulings, or changes in interpretations of existing laws, could materially impact our effective tax rate. Significant reform to U.S. tax laws was enacted in the fourth quarter of 2017 which includes, among other things, changes to tax rates, limitations on the ability to defer U.S. taxation on earnings outside of the United States, and new taxes on profits earned in foreign jurisdictions. These changes to the taxation of our activities could adversely affect the tax treatment of our foreign earnings and impact our worldwide effective tax rate.

We hold cash and cash equivalents at various foreign subsidiaries that may not be readily available to meet domestic cash requirements.

Currently a majority of our cash and cash equivalents is held by our various foreign subsidiaries, in particular our subsidiary in Canada; however, any cash balances held outside the United States may not be readily available, or may not be available without an additional tax burden, to meet our domestic cash requirements. We require a substantial amount of cash in the United States for operating requirements, purchases of property and equipment, and for potential future acquisitions. If we are unable to meet our domestic cash requirements using domestic cash flows from operations, domestic cash and cash equivalents, by settling loans receivable with our foreign subsidiaries, or by domestic borrowing, it may be necessary for us to consider repatriation of earnings. Recent changes to U.S. tax laws may allow for reductions to the potential tax burden on repatriation of foreign cash; however, such actions would require us to record additional income tax expense and remit additional taxes, which could have a material adverse effect on our results of operations, cash flows and financial condition.

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Anti-takeover provisions in our certificate of incorporation, bylaws and Delaware law could make a third party acquisition of us difficult.

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. We are also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of us. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

The “conflict minerals” rule of the SEC has caused us to incur additional expenses, could limit the supply and increase the cost of certain metals used in manufacturing our products, and could make us less competitive in our target markets.

On August 22, 2012, the SEC adopted a rule requiring disclosure of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured by public companies. The rule requires companies to obtain sourcing data from suppliers, engage in supply chain due diligence, and file annually with the SEC a specialized disclosure report. The rule could limit our ability to source at competitive prices. Within our supply chain, we may not be able to sufficiently verify the origins of the relevant minerals used in our products through the data collection and due diligence procedures that we have implemented, which may harm our reputation. Furthermore, we may encounter challenges in satisfying those customers who require that all of the components of our products be certified as conflict free, and if we cannot satisfy these customers, they may choose a competitor’s products. We continue to investigate the presence of conflict materials within our supply chain.

Our stock price has been and is likely to continue to be volatile.

The trading price of our common stock has been and is likely to continue to be highly volatile and subject to wide fluctuations in price. This volatility is in response to various factors, many of which are beyond our control, including:

- actual or anticipated variations in quarterly operating results from historical results or estimates of results prepared by securities analysts;
- developments in patents or other intellectual property rights and litigation;
- new, or changes in, recommendations, guidelines or studies that could affect the use of our products;
- announcements of technological innovations or new products or services by us or our competitors;
- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments in relationships with our partners, customers and suppliers;
- additions or departures of key personnel;
- conditions or trends in the life science, biotechnology and pharmaceutical industries, including the regulatory environment;
- published studies and reports relating to the comparative efficacy of products and markets in which we participate;
- changes in financial estimates by securities analysts;

- general worldwide economic conditions and interest rates;
- the success or lack of success of integrating our acquisitions;
- instability in the United States and other financial markets and the ongoing and possible escalation of unrest internationally, other armed hostilities or further acts or threats of terrorism in the United States or elsewhere;
- sales of our common stock; and

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- the potential adverse impact of the secondary trading of our stock on foreign exchanges, without our permission, which exchanges are subject to less regulatory oversight than the Nasdaq Global Select Market, and the activity of the market makers of our stock on such exchanges, including the risk that such market makers may engage in naked short sales and/or other deceptive trading practices which may artificially depress or otherwise affect the price of our common stock on the Nasdaq Global Select Market.

In addition, the stock market in general, and the Nasdaq Global Select Market and the market for technology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been particular volatility in the market prices of securities of life sciences companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal research and development, manufacturing and administrative facilities are located in Austin, Texas, and consist of approximately 198,600 square feet of leased space pursuant to lease agreements which expire between June 30, 2022 and April 30, 2025. We have options to renew these lease agreements in Austin. We maintain 20,000 square feet of leased office space in The Netherlands, approximately 34,700 square feet of leased office and manufacturing space in Toronto, Canada, approximately 35,000 square feet of leased office and manufacturing space in Madison, Wisconsin, and approximately 64,000 square feet of leased office and manufacturing space in Northbrook, Illinois. In addition, we maintain approximately 7,500 square feet and approximately 2,100 square feet of leased office space in Shanghai and Beijing, respectively, People's Republic of China, approximately 600 square feet of lease office space in Hong Kong and approximately 4,000 square feet of leased office space in Tokyo, Japan. In addition, effective with the closing of the acquisition of EMD Millipore Corporation's flow cytometry portfolio on December 31, 2018, we have approximately 28,000 square feet of leased manufacturing, research and development space in Seattle, Washington.

ITEM 3. LEGAL PROCEEDINGS

When and if it appears probable in management's judgment, and based upon consultation with outside counsel, that we will incur monetary damages or other costs in connection with any claims or proceedings, and such costs can be reasonably estimated, we record the estimated liability in the financial statements. If only a range of estimated losses can be estimated, we record an amount within the range that, in management's judgment, reflects the most likely outcome; if none of the estimates within that range is a better estimate than any other amount, we record the liability at the low end of the range of estimates. Any such accrual would be charged to expense in the appropriate period. We disclose significant contingencies when the loss is not probable and/or the amount of the loss is not estimable, when we believe there is at least a reasonable possibility that a loss has been incurred. We recognize costs associated with legal proceedings in the period in which the services were provided. No material legal proceedings are known to be pending as of December 31, 2018.

ITEM 4. MINE SAFETY DISCLOSURES

None.

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PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol "LMNX."

Holders

As of February 25, 2019, we had 418 holders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial stockholders represented by these record holders.

Dividends

In February 2017, the Board of Directors initiated a cash dividend program under which the Company anticipates paying a regular quarterly cash dividend. Future declarations of quarterly dividends and the establishment of future record and payment dates are subject to the final determination of the Company's Board of Directors. Our ability to declare dividends may also from time to time be limited by the terms of any applicable credit facility. Luminex does not currently have a credit facility.

During 2018, the Company paid dividends on common stock as follows:

2018	Dividend per share	Payment Date
First Quarter	$0.06	April 13, 2018
Second Quarter	$0.06	July 13, 2018
Third Quarter	$0.06	October 12, 2018
Fourth Quarter	$0.06	January 10, 2019

On February 8, 2019, we announced that our Board declared a quarterly cash dividend of $0.06 per share of common stock to be paid to shareholders of record as of the close of business on March 21, 2019 with a payment date of April 11, 2019.

Recent Sales of Unregistered Securities

There were no sales of unregistered securities of Luminex during the twelve months ended December 31, 2018.

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Performance Graph

The following graph compares the change in Luminex's cumulative total stockholder return on its common shares with the Nasdaq Composite Index and the Nasdaq Biotechnology Index.

	12/13	12/14	12/15	12/16	12/17	12/18
Luminex Corporation	100.00	96.70	110.26	104.28	102.79	121.72
Nasdaq Composite	100.00	114.62	122.81	133.19	172.11	165.84
Nasdaq Biotechnology	100.00	131.71	140.56	112.25	133.67	121.24

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Issuer Purchases of Equity Securities

The stock repurchase activity for the fourth quarter of 2018 was as follows:

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased[1]	Average Price Paid per Share ($)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
10/1/2018 - 10/31/2018	10,105	$ 27.25	—	$ —
11/1/2018 - 11/30/2018	—	—	—	—
12/1/2018 - 12/31/2018	107	28.42	—	—
Total Fourth Quarter	10,212	$ 27.26	—	$ —

[1] Total shares purchased includes shares attributable to the withholding of shares by Luminex to satisfy the payment of tax obligations related to the vesting of restricted shares.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with the Consolidated Financial Statements and Notes thereto and with Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other financial data included elsewhere in this Annual Report on Form 10-K. The consolidated statement of comprehensive income data for the years ended December 31, 2018, 2017 and 2016 and the consolidated balance sheet data at December 31, 2018 and 2017 are derived from the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The consolidated results of operations data for the years ended December 31, 2015 and 2014 and the consolidated balance sheet data at December 31, 2016, 2015 and 2014 are derived from audited consolidated financial statements not included in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands, except per share data)				
Consolidated Results of Operations Data:					
Total revenue	$315,818	$306,571	$270,639	$237,708	$226,983
Gross profit	195,491	199,046	179,655	168,707	159,852
Income from operations	27,846	37,153	20,986	37,357	28,137
Net income	$18,508	$29,423	$13,814	$36,861	$39,043
Net income per common share, basic	$0.42	$0.67	$0.32	$0.88	$0.94
Shares used in computing net income per common share (basic)	43,727	43,173	42,584	42,091	41,558
Net income per common share, diluted	$0.41	$0.67	$0.32	$0.86	$0.93
Shares used in computing net income per common share (diluted)	44,291	43,300	43,013	42,637	42,156

	At December 31,				
	2018	2017	2016	2015	2014
Consolidated Balance Sheet Data:	(in thousands)				
Cash and cash equivalents	$76,441	$127,112	$93,452	$128,546	$91,694
Short-term investments	—	—	—	11,988	—
Long-term investments	—	—	—	7,459	15,975
Working capital	151,369	179,393	133,537	182,294	146,654

Total assets	525,175	490,516	450,716	402,556	357,526
Total long-term debt	—	—	—	—	—
Total stockholders' equity	467,656	437,907	403,679	368,536	319,994
Dividends declared per share	$0.24	$0.24	$—	$—	$—

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following information should be read in conjunction with the Consolidated Financial Statements and the accompanying Notes included below in Item 8 and "Risk Factors" included above in Item 1A of this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We develop, manufacture and sell proprietary biological testing technologies and products with applications throughout the life sciences industries, including diagnostics and research. These industries depend on a broad range of tests, called assays, to perform diagnostic testing and conduct life science research.

We primarily serve the life sciences industries by marketing products, including our specific testing equipment, called systems, and assays, to various types of testing laboratories. We have a large base of installed systems that has grown primarily from the following:

- placements made by customers within our Licensed Technologies Group (LTG), previously referred to as our "Partner Business", which customers either:
  - license our xMAP technology and develop products that incorporate our xMAP technology into products that they then sell to end users, or
  - purchase our proprietary xMAP laboratory instrumentation and our proprietary xMAP microspheres and sell xMAP-based assays and/or xMAP-based testing services, which run on the xMAP instrumentation, and pay a royalty to us; and
- in addition, we utilize a direct sales force that focuses on the sale of molecular diagnostic assays that run on our systems.

As of December 31, 2018, Luminex had 74 strategic partners, of which 50 have released commercialized reagent-based products utilizing our technology. Our remaining LTG customers are in various stages of development and commercialization of products that incorporate our technology.

Luminex has a number of forms of revenue that result from our business model:

- System revenue is generated from the sale of our xMAP multiplexing analyzers and peripherals and our VERIGENE readers and processors.
- Consumable revenue is generated from the sale of our dyed polystyrene microspheres, along with sheath and drive fluid. Our larger commercial and development partners often purchase these consumables in bulk to minimize the number of incoming qualification events and to allow for longer development and production runs.
- Royalty revenue is generated when a partner sells our proprietary microspheres to an end user, when a partner sells a kit incorporating our proprietary microspheres to an end user or when a partner utilizes a kit to provide a testing result to an end user. End users can be facilities such as testing labs, development facilities and research facilities that buy prepared kits and have specific testing needs or testing service companies that provide assay results to pharmaceutical

research companies or physicians.

Assay revenue is generated primarily from four sources: (i) sale of our branded kits, which are a combination of chemical and biological reagents and our proprietary xMAP bead technology used to perform diagnostic and research assays on samples, (ii) real-time PCR and multiplexed PCR assays using our proprietary MultiCode technology, (iii) ARIES® cassettes designed to run a fully automated, sample to answer molecular assay on the ARIES® System, and (iv) VERIGENE test cartridges, a sample to answer molecular assay designed to target infections in the bloodstream, respiratory tract, and gastrointestinal tract on the VERIGENE System.

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- Service revenue is generated when a partner or other owner of a system purchases a service contract from us after the standard warranty has expired or pays us for our time and materials to service instruments. Service contract revenue is amortized over the life of the contract and the costs associated with those contracts are recognized as incurred.

- Other revenue consists of items such as training, shipping, parts sales, license revenue, grant revenue, contract research and development fees, milestone revenue and other items that individually amounted to less than 2.5% of total revenue in 2018.

2018 Highlights

- Consolidated revenue was $315.8 million for 2018, representing a 3% increase over revenue for 2017.

- Assay revenue of $156.7 million for 2018, representing a 1% increase over 2017. Excluding sales to LabCorp, assay revenue increased 14% from 2017.

- System shipments of 1,131 multiplexing analyzers, which included Luminex® 100/200™ Systems, MAGPIX Systems and FLEXMAP 3D Systems, up 8% from a year ago, resulting in cumulative life-to-date multiplexing analyzer shipments of 15,979 (some of which may be retired or otherwise not in use).

- Sample to answer product revenue increased for 2018 by $15.0 million, or 36%, from 2017.

- Royalty revenue reflecting over $566.1 million of royalty-bearing end user sales on our technology for 2018, an 11% increase over 2017.

- On December 31, 2018, the Company closed the acquisition of EMD Millipore Corporation’s flow cytometry portfolio for $69.9 million in cash plus approximately $5.1 million in committed inventory purchases.

2018 Acquisition of EMD Millipore Corporation’s flow cytometry portfolio

On December 31, 2018, Luminex completed its acquisition (the Acquisition) of EMD Millipore Corporation’s flow cytometry portfolio for $75 million, consisting of approximately $69.9 million to be paid under a Share and Asset Purchase Agreement (the Purchase Agreement) and approximately $5.1 million in committed inventory purchases, both of which are subject to adjustment. Luminex financed the acquisition with cash on hand, and acquired 100% of the shares and equity of Amnis Corporation, a Washington corporation (Amnis), a wholly owned subsidiary of EMD Millipore Corporation, a Massachusetts corporation (itself an affiliate of Merck KgaA), and certain other assets owned by other affiliates of Merck KgaA (MilliporeSigma).

The Acquisition expands Luminex’s existing offering of flow-based detection systems, which is centered around our innovative xMAP® multiplexing technology, with more than 15,000 xMAP systems sold worldwide. MilliporeSigma’s flow cytometry portfolio includes Amnis, a family of imaging flow cytometry products for cell-based analysis, as well as the Guava and Muse portfolio of products, which are economical systems based on microcapillary technologies. The results of operations for the Acquisition will be included in Luminex’s consolidated financial statements beginning January 1, 2019.

As Luminex integrates the Acquisition in our systems and processes, we expect the gross margins on the acquired portfolio to negatively impact our consolidated gross margins; however, we expect synergies realized from the Acquisition, increased sales volumes and the commercialization of the next generation Guava System to increase these gross margins in the long-term.

Material Customer Activity

As previously stated in our recent annual and quarterly filings, LabCorp has elected to develop the next iteration of one of its women's health products with another party and is also anticipated to cease purchasing CF products from us by the end of 2019. We previously negotiated significant minimum women's health purchases from LabCorp, pursuant to which LabCorp committed to acquire no less than $63.1 million of our women's health products from January 1, 2017 through June 30, 2018. During the quarter ended June 30, 2018, LabCorp met its purchase requirements under that agreement and indicated it will not make further purchases from us of the women's health products covered by such agreement. Separately and based on an extension agreement entered into in the third quarter of 2017, the Company will continue to sell its CF products to LabCorp through at least the end of 2019. The loss of the women's health LabCorp business, and the anticipated future loss of other products traditionally sold to LabCorp (which we expect to occur with products other than CF, as discussed above), could have a material adverse effect on our growth and future results of operations if we are unable to effectively attract new customers and/or increase our sales with existing customers.

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During 2018, LabCorp represented total revenue of $47.3 million. That revenue was categorized as follows: women's health - $23.2 million; CF related - $12.4 million; and all other ancillary products - $11.7 million. During 2017, LabCorp represented total revenue of $61.1 million, and was categorized as follows: women's health - $36.1 million; CF - $13.3 million; and all other ancillary products - $11.7 million. As noted above, LabCorp has met its purchase commitment for women's health products and will no longer be placing material orders for the women's health portfolio. The remainder of the women's health products purchased by LabCorp have also been transitioned to another party. LabCorp orders for our CF products are expected to continue through at least the end of 2019. Orders by LabCorp for other ancillary products are at risk for a potential material reduction in 2019.

Consumables Sales and Royalty Revenue Trends

We have experienced significant fluctuations in consumable revenue in the past. Year-over-year changes in consumable revenue have been an increase of $0.8 million, an increase of $0.7 million, and an increase of $5.3 million in 2018, 2017, and 2016 respectively. While the changes over the past two years have not been significant, fluctuations can manifest through periodic changes in volume from our largest purchasing partners. These partners account for more than 69% of our total consumable sales volume. We expect these fluctuations to continue as the ordering patterns and inventory levels of our largest bulk purchasing partners remain variable. Additionally, even though we experience variability in consumable revenue, the key indicator of the success of our partners' commercialization efforts is the rising level of royalties and reported royalty-bearing sales.

Future Operations

We expect our areas of focus over the next twelve months to be:

- delivering on our revenue growth goals;
- accelerating development and commercialization of the assays on our sample to answer diagnostic systems;
- integrating the flow cytometry business we acquired from EMD Millipore Corporation and ensuring that we retain and recruit talent, including for support functions and key positions not included with this acquisition;
- increasing the growth of our LTG revenue through enrichment of our existing partner relationships and the addition of new partners;
- completing development and commercialization of the next generation sample to answer system, VERIGENE II, our next generation xMAP System, SENSIPLEX, and our next generation Guava instrument, Guava Next Gen;
- improvement of ARIES® and VERIGENE gross margins;
- placements of our VERIGENE and ARIES® Systems, our sample to answer platforms and assays;
- maintenance and improvement of our existing products and the timely development, completion and successful commercial launch of our pipeline products;
- adoption and use of our platforms and consumables by our customers for their testing services;
-

expansion and enhancement of our installed base of systems and our market position within our identified target market segments; and

- monitoring and mitigating the effect of the ongoing uncertainty in global finance markets and changes in government funding on planned purchases by end users.

We anticipate continued revenue concentration in our higher margin items (assays, consumables and royalties). Additionally, we believe that a sustained investment in research and development is necessary in order to meet the needs of our marketplace and provide a sustainable new product pipeline. We may experience volatility in research and development expenses as a percentage of revenue on a quarterly basis as a result of the timing of development expenses, clinical validation and clinical trials in advance of the commercial launch of our new products.

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CRITICAL ACCOUNTING POLICIES

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. The following is a discussion of our most critical accounting policies used in the preparation of our financial statements, and the judgments and estimates involved under each. We also have other significant accounting policies that do not involve critical accounting estimates because they do not generally require us to make estimates and judgments that are difficult or subjective. These are described in Note 1 of our Consolidated Financial Statements provided herein in Item 8. Estimates and assumptions are reviewed periodically. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition and Performance Obligations: Revenue is generated primarily from the sale of the Company's products and related services, which are primarily support and maintenance services on the Company's systems. The Company recognizes product revenue when the Customer obtains control of the Company's product, which typically occurs upon shipment or delivery to the Customer depending upon the shipping terms. We treat shipping and handling costs performed after a customer obtains control of the good as a fulfillment cost. Our customers do not typically have any contractual rights of return outside of our warranty provisions. The Company has allowed few returns to date and believes that returns of its products will be minimal.

Royalties: For arrangements that include sales-based royalties, including minimum payments, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation, to which some or all of the royalty has been allocated, has been satisfied. This is a change from how the Company has historically treated royalty payments, by recognizing royalty revenue when our strategic partners reported the end-user sales to the Company, and is primarily the basis for our cumulative adjustment as of January 1, 2018 to retained earnings of $10.6 million before related tax impacts or $8.1 million net of related tax impacts. Royalty payments are typically received when our strategic partners report the end-user sales to the Company.

Reagent Rentals: The Company provides systems and certain other hardware to customers through reagent rental agreements, under which the customers commit to purchasing minimum quantities of disposable products at a stated price over a defined contract term, which is normally two to three years. Instead of rental payments, the Company recovers the cost of providing the system and other hardware in the amount charged for assays. Revenue is recognized over the defined contract term as assays are shipped. The depreciation costs associated with the system and other hardware are charged to cost of sales on a straight-line basis over the estimated life of the system. The costs to maintain these instruments in the field are charged to cost of sales as incurred. The Company began reclassifying the portion of reagent rental revenue associated with the recovery of the cost of providing the system and other hardware in reagent rental agreements from assay revenue to system revenue effective January 1, 2018. This change will not have any impact on top line revenue and the Company does not anticipate any material effects to its revenue categorization.

Warranties: The Company provides a limited, assurance-type warranty, typically for twelve months from installation for the systems sold to end customers and fifteen months for the systems sold to partners. The Company accrues for the estimated cost of initial product warranties at the time revenue is recognized. While we engage in product quality programs and processes, our warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. While management believes that adequate reserve has been

made in the consolidated financial statements for product warranties, should actual product failure rates, material usage or service delivery costs differ from our estimates, revisions to the estimated warranty liability would be required. However, we do not believe this estimate is subject to significant variability.

License Revenues: The Company enters into out-licensing agreements, under which it licenses certain rights to its technology to third parties. These licenses are typically not distinct, as the customer cannot benefit from the license on its own, and do not have significant standalone functionality, but represent single performance obligations together with the sales of our consumables, systems and assays. The terms of these arrangements typically include payment to the Company of non-refundable, up-front license fees and can extend up to twenty years, although some of our current agreements extend through 2027. Each of these payments results in license revenues which are recognized ratably over time and are included in other revenues, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues. Deferred revenues related to these out-licensing agreements are shown in contract liabilities in the table below.

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Service Agreements: Revenue from extended service agreements is deferred when payment is received in advance of the performance obligation being satisfied or completed. Luminex provides an integrated service of maintenance and related activities for equipment sold to customers, where the nature of the overall promise is to provide a stand-ready service. As such, the performance obligation is recognized as a series of distinct service periods and the service revenue is recognized ratably over the term of the agreement. The extended service agreements typically range from one to four years and payment is typically received up-front.

Reserves for Variable Consideration: Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from discounts and any other allowances that are offered within contracts between the Company and its customers relating to the Company's sales of its products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable. Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as the Company's historical experience, current contractual requirements, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of each contract. The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period when such variances become known.

We adopted new revenue accounting guidance effective January 1, 2018, which will impact the amount and timing of our future revenue recognition. For further discussion, see Note 18, "Revenue Recognition", in our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Inventory. Inventories are valued at the lower of cost and net realizable value. Cost is determined according to the standard cost method. Net realizable value is defined as the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. Inventories have been written down through an allowance for excess and obsolete inventories. The two major components of the allowance for excess and obsolete inventory are (i) a specific write-down for inventory items that we no longer use in the manufacture of our products or that no longer meet our specifications and (ii) a write-down against slow moving items for potential obsolescence. Inventory is reviewed on a regular basis and adjusted based on management's review of inventories on hand compared to estimated future usage and sales. While management believes that adequate write-downs for inventory obsolescence have been made in the consolidated financial statements, scientific and technological advances will continue and we could experience additional inventory write-downs in the future. However, we do not believe this estimate is subject to significant variability.

Purchase Price Allocation, Intangibles and Goodwill. The purchase price allocation for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired, including in-process research and development, and liabilities assumed based on their respective fair values. Intangible assets with definite lives are amortized over the assets' estimated useful lives using the straight-line method. We periodically review the estimated useful lives of our identifiable intangible assets, taking into consideration any events or circumstances that might result in a diminished fair value or revised useful life.

Goodwill represents the excess of the cost over the fair value of the assets of the acquired business. We evaluate the carrying value of goodwill on a reporting unit level annually, on October 1st of each year, or more frequently if there is evidence that certain events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. In 2018 and 2017, the Company estimated the fair value of the reporting unit using a fair-value

approach based on the market capitalization. This analysis requires a comparison of the carrying value of the reporting unit to the estimated fair value of the reporting unit. Determining the fair value of goodwill is subjective in nature and often involves the use of estimates and assumptions including, without limitation, use of estimates of future prices and volumes for the Company's products, capital needs, economic trends and other factors which are inherently difficult to forecast. Our annual test, performed on the first day of the fourth quarter, did not result in an impairment charge for 2018 or 2017 as the estimated fair value of our reporting unit exceeded the carrying value by a significant enough amount that any reasonably likely change in the assumptions used in the analysis would not cause the carrying value to exceed the estimated fair value for the reporting unit as determined under our analysis.

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Accounting for Income Taxes. We calculate our provision for income taxes using the asset and liability method, under which deferred tax assets and liabilities are recognized by identifying the temporary differences arising from the different treatment of items for tax and accounting purposes. In determining the future tax consequences of events that have been recognized in our financial statements or tax returns, judgment is required. Differences between the anticipated and actual outcomes of these future tax consequences could have a material impact on our consolidated results of operations or financial position. The recognition of deferred tax assets is reduced by a valuation allowance if it is more likely than not that the tax benefits will not be realized. We regularly review our deferred tax assets for recoverability and establish a valuation allowance based on historical income, projected future income, the expected timing of the reversals of existing temporary differences and the implementation of tax-planning strategies. The excess of financial reporting basis over tax basis of our foreign subsidiaries are considered permanently reinvested, with the exception of the Canadian subsidiary. Accordingly, provision for withholding taxes on certain earnings has only been provided for this subsidiary.

The GAAP guidance requires recognition of the impact of a tax position in our financial statements only if that position is more likely than not to be sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense. Determining the consolidated provision for income taxes involves judgments, estimates and the application of complex tax regulations. We are required to provide for income taxes in each of the jurisdictions where we operate, including estimated liabilities for uncertain tax positions. Although we believe that we have provided adequate liabilities for uncertain tax positions, the actual liability resulting from examinations by taxing authorities could differ from the recorded income tax liabilities and could result in additional income tax expense having a material impact on our consolidated results of operations. Changes of estimates in our income tax liabilities are reflected in our income tax provision in the period in which the factors resulting in the change to our estimate become known to us. We benefit from research tax credit incentives in the U.S. and Canada extended to taxpayers engaged in qualified research and experimental activities while carrying on a trade or business.

Significant reform of the Internal Revenue Code was signed into legislation on December 22, 2017 pursuant to the Tax Cuts and Jobs Act (“the Tax Act”). This legislation includes, among other things, changes to U.S. federal tax rates and the migration from a “worldwide” system of taxation to a territorial system. However, U.S. tax reform modifications to the taxation of foreign profits and changes to deductibility of U.S operational expenses will have an ongoing impact to the tax estimates in our financial statements and may not be beneficial. Currently, there is uncertainty regarding the interpretation and application of the Tax Act. These uncertainties could materially impact our tax estimates reflected in the financial statements and could be adverse in future years.

In addition, the Affordable Care Act includes tax-related provisions. Specifically, the law requires manufacturers, producers and importers of medical devices to pay a 2.3% excise tax on U.S. sales of certain medical devices as of January 1, 2013. Our products that have received FDA approval fall under the government classification and are subject to the excise tax. However, a moratorium on the tax took effect on January 1, 2016 and has been extended through December 31, 2019.

Stock compensation. All stock-based compensation cost, including grants of stock options, restricted stock units and shares issued under the Company’s employee stock purchase plan, is measured at the grant date based on the fair value of the award and is recognized as an expense on a straight-line basis over the requisite service period, which is generally the vesting period. The fair value of our stock options is estimated using the Black-Scholes option pricing model. The Black-Scholes valuation calculation requires us to estimate key assumptions such as expected volatility, expected term and risk-free rate of return. Calculation of expected volatility is based on historical volatility. The expected term is calculated using the contractual term of the options as well as an analysis of our historical exercises of stock options. The estimate of the risk-free rate of return is based on the U.S. Treasury yield curve in effect at the time of grant. The dividend yield is based on our history and expectation of dividend payouts at the time of grant.

The amount of stock-based compensation expense recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. As part of the requirements of ASC 718 “Stock Compensation”, the Company is required to estimate potential forfeitures of stock grants and adjust compensation cost recorded accordingly. The estimate of forfeitures is based on historical forfeiture performance and will be adjusted over the requisite service period to the extent that actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment in the period of evaluation and will also impact the amount of stock compensation expense to be recognized in future periods. Ultimately, the actual expense recognized over the vesting period will only be for those awards that vest, except for the limited number of market based awards under long term incentive plans. If we use different assumptions for estimating stock-based compensation expense in future periods or if actual forfeitures differ materially from our estimated forfeitures, the change in our stock-based compensation expense could materially affect our operating income, net income and net income per share.

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CONSOLIDATED RESULTS OF OPERATIONS

The following table sets forth the percentage of total revenue of certain items in the Consolidated Results of Operations. The financial information and the discussion below should be read in conjunction with the Consolidated Financial Statements and Notes thereto.

	Year Ended December 31,		
	2018	2017	2016
Revenue	100 %	100 %	100 %
Cost of revenue	38 %	35 %	34 %
Gross profit	62 %	65 %	66 %
Operating expenses:			
Research and development expense	15 %	15 %	18 %
Selling, general and administrative expense	35 %	35 %	37 %
Amortization of acquired intangible assets	3 %	3 %	3 %
Restructuring	— %	— %	1 %
Total operating expenses	53 %	53 %	59 %
Income from operations	9 %	12 %	8 %
Other income, net	— %	— %	— %
Debt prepayment penalty	— %	— %	(1)%
Settlement of litigation	— %	— %	— %
Income taxes	(3)%	(3)%	(2)%
Net income	6 %	10 %	5 %

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

	Year Ended December 31,			
	2018	2017	Variance	Variance (%)
	(dollars in thousands)			
Revenue	$315,818	$306,571	$9,247	3 %
Gross profit	$195,491	$199,046	$(3,555)	(2)%
Gross margin percentage	62 %	65 %	(3)%	N/A
Operating expenses	$167,645	$161,893	$5,752	4 %
Income from operations	$27,846	$37,153	$(9,307)	(25)%
Net income	$18,508	$29,423	$(10,915)	(37)%

Total revenue increased by 3% to $315.8 million for the year ended December 31, 2018 from $306.6 million in 2017. This increase was driven primarily by an increase in our automated assays, royalty and system revenue. Automated assay revenue, which is comprised of VERIGENE and ARIES® assays, grew 36% to more than $56 million for the year ended December 31, 2018 from the prior year. These increases were partially offset by a reduction in our non-automated assay revenue, mainly attributable to the decrease in LabCorp sales. Non-automated assay revenue comprised 64% of total assay revenue for the year ended December 31, 2018 compared to 73% for 2017. Excluding LabCorp sales, total revenue increased 9% for the year ended December 31, 2018, from the prior year.

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A breakdown of revenue for the years ended December 31, 2018 and 2017 is as follows:

	Year Ended December 31,			
	2018	2017	Variance	Variance (%)
	(dollars in thousands)			
System sales	$39,986	$38,651	$1,335	3 %
Consumable sales	50,144	49,319	825	2 %
Royalty revenue	49,394	44,704	4,690	10 %
Assay revenue	156,714	154,907	1,807	1 %
Service revenue	12,159	11,470	689	6 %
Other revenue	7,421	7,520	(99)	(1)%
	$315,818	$306,571	$9,247	3 %

We continue to have revenue concentration in a limited number of customers. In 2018, the top five customers, by revenue, accounted for 42% of total revenue down from 48% of total revenue in 2017. In particular, our two largest customers by revenue accounted for 29% of 2018 total revenue (15% and 14%, respectively) a decrease from 35% of 2017 total revenue (20% and 15%, respectively). This decrease is mainly attributable to the reduction of LabCorp sales and we anticipate this trend to continue as discussed under Material Customer Activity. No other customer accounted for more than 6% of total revenue in 2018 or 2017.

Under the new revenue recognition guidance effective January 1, 2018, the system portion of reagent rental revenue is recognized in system revenue. Revenue from the sale of systems and peripheral components increased 3% to $40.0 million for the year ended December 31, 2018 from $38.7 million for the year ended December 31, 2017. This increase is primarily the result of higher sample to answer reagent rental system placements for the year ended December 31, 2018, which grew 61% over the prior year, and resulted in a $2.5 million reclassification of revenue from assay to system revenue in the current year. This was partially offset by a change in customer sales mix, which lowered the average sales price of system units. We sold 1,131 multiplexing analyzers in 2018, as compared to 1,066 multiplexing analyzers sold in 2017, bringing total multiplexing analyzer shipments since inception to 15,979 as of December 31, 2018, some of which may be retired or otherwise not in use. For the year ended December 31, 2018, our five highest selling partners accounted for 882 systems, or 78%, of total multiplexing analyzers sold, whereas, our five highest selling partners in 2017 accounted for 779, or 73%, of total multiplexing analyzers sold.

Consumable sales, comprised of microspheres and sheath fluid, increased 2% to $50.1 million in 2018 from $49.3 million in 2017. During the year ended December 31, 2018, we had 74 bulk purchases of consumables totaling approximately $38.8 million (77% of total consumable revenue), ranging from $0.1 million to $3.8 million, as compared with 70 bulk purchases totaling approximately $37.3 million (76% of total consumable revenue) in the year ended December 31, 2017. The modest increase in bulk purchases in 2018 is the primary driver to the increase in consumable revenue from the prior year. We expect fluctuations in consumable sales on an ongoing basis. Partners who reported royalty-bearing sales accounted for $32.8 million, or 65%, of consumable sales for the year ended December 31, 2018 compared to $34.7 million, or 70%, of the total consumable sales for the year ended December 31, 2017.

Royalty revenue, which results when our partners sell products or testing services incorporating our technology, increased 10% to $49.4 million for the year ended December 31, 2018 from $44.7 million for the year ended December 31, 2017. This increase is the result of higher royalty minimums, audit findings and other adjustments of $2.5 million (collectively) and higher base royalties of $2.2 million, which we believe is mainly the result of menu expansion and increased utilization of our partners' assays on our technology. We expect modest fluctuations in the royalties submitted quarter to quarter based upon the varying contractual terms, differing reporting and payment

requirements, and the addition of new partners. Our partners' end user sales may reflect volatility from quarter to quarter and, therefore, that same volatility is reflected in our reported royalty revenues on a quarterly basis.

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Assay revenue increased 1% to $156.7 million for the year ended December 31, 2018 from $154.9 million for the year ended December 31, 2017, primarily attributable to an increase in our sample to answer assay revenue, which consists of VERIGENE and ARIES® assay sales. Our sample to answer assay revenue grew 36% to $56.4 million for the year ended December 31, 2018 from $41.4 million in 2017. These increases were partially offset by reductions in our non-automated testing assays. Revenue for our non-automated infectious disease testing products decreased by 11%, driven mainly by the reduction in LabCorp's non-CF related sales of approximately $13 million to $36.9 million, from $49.9 million in 2017, while our genetic testing assays decreased by 12% from 2017. The decrease in revenue from our genetic testing products was attributable to pricing and reimbursement challenges within the pharmacogenetic market segment, in addition to declining sales of CF assays from LabCorp of $0.8 million for the year ended December 31, 2018. Our largest customer, by revenue, accounted for 29% of total assay revenue for the year ended December 31, 2018 compared to 38% for the year ended December 31, 2017. No other customer accounted for more than 10% of total assay revenue during those periods. As discussed under "Material Customer Activity" and previously disclosed in our prior quarterly reports, our largest assay customer, LabCorp, has developed the next iteration of their women's health portfolio with another party, which negatively impacted our assay revenue in 2018. Excluding LabCorp sales, assay revenue increased 9% for the year ended December 31, 2018 as compared to the year ended December 31, 2017.

Service revenue, comprised of extended warranty contracts earned ratably over the term of a contract and time and materials for billable service work not under an extended warranty contract, increased 6% to $12.2 million during 2018 from $11.5 million in 2017, primarily driven by the increase in the number of systems covered under extended service agreements. At December 31, 2018, we had 2,311 Luminex systems covered under extended service agreements and $5.3 million in deferred revenue related to those contracts. At December 31, 2017, we had 1,989 Luminex systems covered under extended service agreements and $4.8 million in deferred revenue related to those contracts.

Other revenue, which includes training revenue, shipping revenue, miscellaneous part sales, amortized license fees, milestone payments and revenue from agreements with U.S. government agencies, decreased to $7.4 million for the year ended December 31, 2018 compared to $7.5 million for the year ended December 31, 2017, primarily driven by an increase in amounts paid towards global purchasing organizations, which are accounted for as a reduction of revenue.

Gross Profit. Gross profit decreased to $195.5 million for the year ended December 31, 2018, as compared to $199.0 million for the year ended December 31, 2017. Gross margin (gross profit as a percentage of total revenue) decreased to 62% for the year ended December 31, 2018, from 65% for the year ended December 31, 2017. This decrease in gross margin is primarily attributable to the decline in LabCorp's assay purchases, which typically carry a higher gross margin, and the absorption of higher manufacturing expenses for the year ended December 31, 2018. These impacts were partially offset by a favorable change in sales mix from other higher margin items, most notably, royalty and consumable revenue. Concentration of sales in our higher margin items (assays, consumables and royalties) was 81% of revenue for each of the years ended December 31, 2018 and 2017. We anticipate continued fluctuation in gross margin and related gross profit primarily as a result of variability in consumable and system purchases and seasonality effects inherent in our assay revenue.

Research and Development Expense. Research and development expense increased to $47.2 million for the year ended December 31, 2018 from $45.7 million in 2017, but as a percentage of total revenue remained constant at 15%. The increase in research and development expense was primarily a result of the focus of our efforts in the development and commercialization of a pipeline of assays for the ARIES® System and the development and commercialization of the next generation VERIGENE System, VERIGENE II, and assays. Research and development headcount as of December 31, 2018 was 196, as compared to 175 as of December 31, 2017.

Selling, General and Administrative Expense. Selling, general and administrative expenses, excluding the amortization of acquired intangible assets, increased to $111.8 million for the year ended December 31, 2018 from $107.3 million for the year ended December 31, 2017. The increase was primarily attributable to Acquisition related expenses of $2.7 million incurred in late 2018, in addition to higher personnel costs and material expenses stemming from potential customer validations. Selling, general and administrative headcount at December 31, 2018 was 385, as compared to 358 at December 31, 2017. As a percentage of revenue, selling, general and administrative expense, excluding the amortization of acquired intangible assets, remained flat at 35% for the years ended December 31, 2018 and 2017.

Other Income, net. We received a nonrecurring dividend payment of $0.4 million from one of our cost-method investments in the year ended December 31, 2018. See Note 3 - Investments and Other Assets for further details regarding our cost-method investments.

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Income taxes. Our effective tax rate for the year ended December 31, 2018 was 35%, or $9.8 million, as compared to a an effective tax rate of 21%, or $7.7 million, for the year ended December 31, 2017. Significant reform of the Internal Revenue Code was enacted on December 22, 2017 pursuant to the Tax Cuts and Jobs Act ("the Tax Act"). The Tax Act includes, among other things, changes to the U.S. federal tax rates and the migration from a worldwide system of taxation to a territorial system. The incurred tax expense for 2018 and 2017 is primarily driven by the impact of this tax legislation. On December 22, 2017, Staff Accounting Bulletin No. 118 (SAB 118) was issued to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, the Company recorded provisional amounts in 2018 and 2017 related to the enactment date effects of the Tax Act. At December 31, 2018 the Company completed its accounting for all of the enactment-date income tax effects of the Tax Act and recorded a tax benefit of $741,000 for provisional adjustments comprised of (i) increase of $1.9 million to the transition tax related to the Tax Act; (ii) a revaluation of deferred tax assets of $74,000 based upon the future tax rates; and (iii) a reduction of a deferred tax liability for withholding taxes related to our Canadian entity of $2.5 million. In 2018, the Company also recorded approximately $2.1 million of tax expense under the global intangible low-taxed income provisions of the Tax Act which became effective January 1, 2018, and tax expense totaling $1.4 million based on the results of a Canadian income tax audit. In 2017, the Company recorded provisional tax expense totaling $12.6 million related to the effects of the Tax Act, comprised of: (i) a transition tax of $6.7 million related to the Tax Act; (ii) a revaluation of deferred tax assets of $2.7 million based upon the future tax rates; and (iii) establishment of a deferred tax liability for withholding taxes related to our Canadian entity based upon our change in reinvestment assertions of $3.2 million. These tax legislation effects were offset by the valuation allowance release on our Canadian deferred tax assets of $12.5 million in the third quarter of 2017. Other rate impacts are due to the current rate differential between the U.S. and Canada and our research credit benefit.

We expect our worldwide mix of earnings will mainly be taxed in jurisdictions with a top statutory tax rate of 25% in the near term. However, the Tax Act's modifications to the taxation of foreign profits and changes to deductibility of U.S. operational expenses will have an ongoing impact to the tax estimates in our financial statements and may not be beneficial. As a result, we expect our consolidated effective tax rate to be in the 25% to 30% range over the next several years, absent any other significant discrete items. Currently there is uncertainty regarding the interpretation and application of the Tax Act. These uncertainties could materially impact our tax estimates reflected in the financial statements and could be adverse in future years. We continue to assess our business model and its impact in various tax jurisdictions.

Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

	Year Ended December 31,			
	2017	2016	Variance	Variance (%)
	(dollars in thousands)			
Revenue	$306,571	$270,639	$35,932	13 %
Gross profit	$199,046	$179,655	$19,391	11 %
Gross margin percentage	65 %	66 %	(1)%	N/A
Operating expenses	$161,893	$158,669	$3,224	2 %
Income from operations	$37,153	$20,986	$16,167	77 %
Net income	$29,423	$13,814	$15,609	113 %

Total revenue increased by 13% to $306.6 million for the year ended December 31, 2017 from $270.6 million in 2016. This increase was driven primarily by the acquisition of Nanosphere, Inc. (the Nanosphere Acquisition) on June 30,

2016, which contributed approximately 72% of the 13% increase stemming from the full year of activity in 2017 versus a half of a year of activity in 2016. The Nanosphere Acquisition's most significant revenue contribution is with respect to the assay revenue component of our business.

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A breakdown of revenue for the years ended December 31, 2017 and 2016 is as follows:

	Year Ended December 31,			
	2017	2016	Variance	Variance (%)
	(dollars in thousands)			
System sales	$38,651	$37,416	$1,235	3 %
Consumable sales	49,319	48,596	723	1 %
Royalty revenue	44,704	44,045	659	1 %
Assay revenue	154,907	122,064	32,843	27 %
Service revenue	11,470	10,816	654	6 %
Other revenue	7,520	7,702	(182)	(2)%
	$306,571	$270,639	$35,932	13 %

In 2017, the top five customers, by revenue, accounted for 48% of total revenue down from 49% of total revenue in 2016. In particular, our two largest customers by revenue accounted for 35% of 2017 total revenue (20% and 15%, respectively) an increase from 33% of 2016 total revenue (20% and 13%, respectively). No other customer accounted for more than 10% of total revenue in 2017 or 2016.

Revenue from the sale of systems and peripheral components increased 3% to $38.7 million for the year ended December 31, 2017 from $37.4 million for the year ended December 31, 2016. This resulted primarily from the inclusion of a full year of VERIGENE System sales in 2017, which accounted for more than 70% of the 3% increase, as well as a more favorable mix in sales of multiplexing analyzers with fewer sales of LUMINEX 100/200 Systems in 2017 and by more sales of FLEXMAP 3D Systems whose average sales price is higher than the LUMINEX 100/200 Systems. We sold 1,066 multiplexing analyzers in 2017, as compared to 1,098 multiplexing analyzers sold in 2016, bringing total multiplexing analyzer shipments since inception to 14,848 as of December 31, 2017, some of which may be retired or otherwise not in use. For the year ended December 31, 2017, our five highest selling partners accounted for 779 systems, or 73%, of total multiplexing analyzers sold, whereas, our five highest selling partners in 2016 accounted for 776, or 68%, of total multiplexing analyzers sold.

Consumable sales, comprised of microspheres and sheath fluid, increased 1% to $49.3 million in 2017 from $48.6 million in 2016. During the year ended December 31, 2017, we had 70 bulk purchases of consumables totaling approximately $37.3 million (76% of total consumable revenue), ranging from $0.1 million to $6.4 million, as compared with 78 bulk purchases totaling approximately $37.5 million (77% of total consumable revenue) in the year ended December 31, 2016. The increase in non-bulk purchases in 2017 was the primary driver to the increase in consumable revenue from the prior year. Partners who reported royalty-bearing sales accounted for $34.7 million, or 70%, of consumable sales for the year ended December 31, 2017 compared to $33.3 million, or 68%, of the total consumable sales for the year ended December 31, 2016.

Royalty revenue, which results when our partners sell products or testing services incorporating our technology, increased 1% to $44.7 million for the year ended December 31, 2017 from $44 million for the year ended December 31, 2016. This increase was primarily the result of an increase in base royalties of $0.5 million, which we believe was mainly the result of menu expansion and increased utilization of our partners' assays on our technology.

Assay revenue increased 27% to $154.9 million for the year ended December 31, 2017 from $122.1 million for the year ended December 31, 2016, primarily attributable to an increase in our sample to answer assay revenue, which consists of VERIGENE and ARIES® assay sales, in addition to increased sales of our non-automated infectious disease testing assays. The increase in our sample to answer assay revenue accounted for 80% of the 27% increase, driven primarily by the inclusion of a full year of VERIGENE assay sales in 2017. Revenue for our non-automated

infectious disease testing products increased by 15% while our genetic testing assays decreased by 15% from 2016. The decrease in revenue from our genetic testing products was attributable to pricing and reimbursement challenges within the pharmacogenetic market segment and the departure of a significant customer, causing us to shift our focus towards infectious disease testing. The VERIGENE assay revenue stream represents approximately 25% of total assay revenue for the year ended December 31, 2017, and consisted primarily of our sample to answer clinical tests. Our largest customer, by revenue, accounted for 38% of total assay revenue for the year ended December 31, 2017 compared to 43% for the year ended December 31, 2016. No other customer accounted for more than 10% of total assay revenue during those periods.

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Service revenue, comprised of extended warranty contracts earned ratably over the term of a contract and time and materials for billable service work not under an extended warranty contract, increased 6% to $11.5 million during 2017 from $10.8 million in 2016. This increase was primarily attributable to the Acquisition and having a full year of service activity reflected in 2017. At December 31, 2017, we had 1,989 Luminex systems covered under extended service agreements and $4.8 million in deferred revenue related to those contracts. At December 31, 2016, we had 1,940 Luminex systems covered under extended service agreements and $5.2 million in deferred revenue related to those contracts.

Other revenue, which includes training revenue, shipping revenue, miscellaneous part sales, amortized license fees, milestone payments and revenue from agreements with U.S. government agencies, decreased to $7.5 million for the year ended December 31, 2017 compared to $7.7 million for the year ended December 31, 2016, primarily driven by a reduction in government contract revenue. We expect this trend to continue in the near term as our focus has shifted away from government contract opportunities.

Gross Profit. Gross profit increased to $199.0 million for the year ended December 31, 2017, as compared to $179.7 million for the year ended December 31, 2016. However, gross margin (gross profit as a percentage of total revenue) was 65% for the year ended December 31, 2017, down from 66% for the year ended December 31, 2016. The decrease in gross margin percentage was primarily attributable to the Nanosphere Acquisition. Concentration of sales in our higher margin items (assays, consumables and royalties) was 81% of revenue for the year ended December 31, 2017 compared to 79% for the year ended December 31, 2016.

Research and Development Expense. Research and development expense decreased to $45.7 million, or 15% of total revenue, for the year ended December 31, 2017 from $48.7 million, or 18% of total revenue, for the year ended December 31, 2016. The decrease in research and development expense was primarily a result of savings from the reorganization in December 2016, which was partially offset by a full year of Nanosphere related expenses in 2017. Research and development headcount as of December 31, 2017 was 175, as compared to 199 as of December 31, 2016.

Selling, General and Administrative Expense. Selling, general and administrative expenses, excluding the amortization of acquired intangible assets, increased to $107.3 million for the year ended December 31, 2017 from $99.5 million for the year ended December 31, 2016. The increase was primarily attributable to the inclusion of a full year of Nanosphere related expenses, in addition to higher personnel costs, partially resulting from one-time employee separation costs. This was partially offset by Nanosphere Acquisition-related transaction costs of $3.2 million incurred in 2016, which did not repeat in 2017. Selling, general and administrative headcount at December 31, 2017 was 358, as compared to 364 at December 31, 2016. As a percentage of revenue, selling, general and administrative expense, excluding the amortization of acquired intangible assets, declined to 35% for 2017 compared to 37% in 2016.

Restructuring costs. We recorded no reorganization charges in 2017 as compared with total pre-tax reorganization charges of $2.5 million in 2016 pertaining to certain employee separation costs, of which $2.3 million was recorded to reorganization costs in our operating expenses and $0.2 million to cost of revenue.

Other Income, net. We incurred $1.5 million in debt retirement fees in 2016 in connection with the payoff of Nanosphere’s debt following the Nanosphere Acquisition.

Income taxes. Our effective tax rate for the year ended December 31, 2017 was 21%, or $7.7 million, as compared to an effective tax rate of 30%, or $5.8 million, for the year ended December 31, 2016. The incurred tax expense for 2017 is primarily driven by the impact of the Tax Act, offset by the valuation allowance release on our Canadian deferred tax assets of $12.5 million in the third quarter of 2017. In accordance with SAB 118, the Company recorded provisional tax expense totaling $12.6 million, comprised of: (i) a transition tax of $6.7 million related to the Tax Act;

(ii) a revaluation of deferred tax assets of $2.7 million based upon the future tax rates; and (iii) establishment of a deferred tax liability for withholding taxes related to our Canadian entity based upon our change in reinvestment assertions of $3.2 million. Other rate impacts were due to the current rate differential between the U.S. and Canada, our research credit benefit and valuation allowance releases on the deferred tax assets of our Netherlands subsidiary and certain U.S. states. The tax expense for 2016 reflects increases for valuation allowances recorded against U.S. research credits and Dutch net operating losses, in addition to non-deductible costs related to the Acquisition. These tax expense increases were partially offset by tax benefits from not recording a valuation allowance on our Canadian deferred tax assets generated in 2016, from generating new U.S. research credits in 2016, and from the inclusion of book losses for Nanosphere in the U.S. federal consolidated income tax return.

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LIQUIDITY AND CAPITAL RESOURCES

	December 31, 2018	December 31, 2017
	(in thousands)	
Cash and cash equivalents	$76,441	$ 127,112

At December 31, 2018, we held cash and cash equivalents of $76.4 million and had working capital of $151.4 million. At December 31, 2017, we held cash and cash equivalents of $127.1 million and had working capital of $179.4 million. Cash, and cash equivalents decreased by $50.7 million during the year ended December 31, 2018. The decrease in cash and cash equivalents from the prior year is primarily attributable to the purchase of EMD Millipore's flow cytometry business for $65.4 million, net of cash acquired, purchases of property, plant and equipment of $21.3 million and dividends of $10.7 million. These outflows were partially offset by operating cash flows of $50.9 million and $4.6 million of proceeds from employee stock plans and exercises of stock options.

We have funded our operations to date primarily through cash generated from operations and the issuance of equity securities (in conjunction with an initial public offering in 2000, subsequent option exercises, and our follow-on public offering in 2008). Our cash reserves are held directly or indirectly in a variety of short-term, interest-bearing instruments, including non-government sponsored debt securities. We do not have any investments in asset-backed commercial paper, auction rate securities, or mortgage backed or sub-prime style investments.

Cash provided by operations was $50.9 million for the year ended December 31, 2018 as compared with cash provided by operations of $57.4 million for the year ended December 31, 2017. This decrease was primarily attributable to higher operating expenses and lower gross profit in the current year as compared to the year ended December 31, 2018. Cash used in investing activities was $93.5 million for the year ended December 31, 2018 an increase from $17.1 million for 2017. The change in cash flows of investing activities from 2017 to 2018 was primarily attributable to the acquisition of EMD Millipore's flow cytometry business. Currently, exclusive of changes in available-for-sale securities, we expect cash used in investing activities to be primarily for purchases of property and equipment, additional cost-method investments and continued strategic investments or acquisitions.

Cash used in financing activities increased to $8.4 million for the year ended December 31, 2018, from cash used in financing activities of $6.0 million for the year ended December 31, 2017. This change in cash flows used in financing activities was primarily attributable to the payment of four full quarters of dividends in 2018, compared to only three in 2017 due to its initiation in 2017 by the Board of Directors.

Our future capital requirements will depend on a number of factors, including our success in developing and expanding markets for our products, payments under possible future strategic arrangements, continued progress of our research and development of potential products, the timing and outcome of regulatory approvals, the need to acquire licenses to new technology, costs associated with strategic acquisitions including acquisition and integration costs and assumed liabilities, the status of competitive products and potential costs associated with both protecting and defending our intellectual property. Additionally, actions taken as a result of the ongoing internal evaluation of our business could result in expenditures not currently contemplated in our estimates for 2019.

Our short-term projects that are expected to require significant capital to complete are development of the next generation xMAP System, SENSIPLEX, our current in-process research and development of the next generation VERIGENE System, VERIGENE II, on which we began clinical trials in May 2018 and our in-process research and development of the Guava Next Gen. We believe SENSIPLEX ,VERIGENE II and Guava Next Gen will launch commercially in 2020, 2019 and 2019, respectively. The estimated aggregate cost to complete these projects,

including completion of development of the systems, cartridge, software and the initial assay, validation, verification, clinical trials and regulatory submission, is approximately $9.9 million and is included in our research and development budget for 2019 and 2020. We believe that our existing cash and cash equivalents are sufficient to fund our operating expenses, capital equipment requirements and other expected liquidity requirements for the coming twelve months. Factors that could affect our capital requirements, in addition to those listed above, include, without limitation: (i) continued collections of accounts receivable consistent with our historical experience; (ii) our ability to manage our inventory levels consistent with past practices; (iii) volatility in our key partners' consumable purchasing patterns; (iv) execution of partnership agreements that include significant up-front license fees; (v) execution of our stock repurchase and dividend programs from time to time and (vi) executing strategic investment or acquisition agreements requiring significant cash consideration. See also the "Safe Harbor Cautionary Statement" and risk factors of this report.

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In February 2017, the Board of Directors initiated a cash dividend program to pay a regular quarterly cash dividend. The timing and amount of future dividends and stock repurchases will vary based on a number of factors, including future capital requirements for strategic transactions, the availability of financing on acceptable terms, debt service requirements, changes to applicable tax laws or corporate laws, changes to our business model and periodic determination by our Board of Directors that cash dividends are in the best interests of stockholders and are in compliance with applicable laws and agreements of the Company. On February 8, 2019, we announced that our Board declared a quarterly cash dividend of $0.06 per share of common stock to be paid to shareholders of record as of the close of business on March 21, 2019 with a payment date of April 11, 2019.

As previously stated in our recent annual and quarterly filings, LabCorp has elected to develop the next iteration of one of its women's health products with another party. We previously negotiated significant minimum women's health purchases from LabCorp, pursuant to which LabCorp committed to acquire no less than $63.1 million of our women's health products from January 1, 2017 through June 30, 2018. During the quarter ended June 30, 2018, LabCorp met its purchase requirements under that agreement and indicated it will not make further purchases of the women's health products covered by such agreement. Based on an extension agreement entered into in the third quarter of 2017, the Company will continue to sell its Cystic Fibrosis (CF) products to LabCorp through at least the end of 2019. The loss of the women's health LabCorp business, and the anticipated future loss of other products traditionally sold to LabCorp (which we expect to occur with products other than CF, as discussed above), could have a material adverse effect on our growth and future results of operations.

During 2018, LabCorp represented total revenue of $47.3 million. That revenue was categorized as follows: women's health - $23.2 million; CF related - $12.4 million; and all other ancillary products - $11.7 million. As noted above, LabCorp has met its purchase commitment for women's health products and will no longer be placing material orders for the women's health portfolio. The remainder of the women's health products purchased by LabCorp have also been transitioned to another party. LabCorp orders for our CF products are expected to continue through at least the end of 2019. Orders by LabCorp for other ancillary products are at risk for a potential material reduction throughout 2019.

We hold cash and cash equivalents at various foreign subsidiaries. As a result of reductions to the U.S. taxation of dividends from foreign subsidiaries under the Tax Act and continued profitability of our Canadian subsidiary, in future years we may repatriate earnings of our Canadian subsidiary. The cash and cash equivalents held by this subsidiary may be more readily available to meet domestic cash requirements in the next year, but will continue to be subject to foreign withholding tax that would be incurred upon repatriation. We anticipate that cash and cash equivalents held by all other foreign subsidiaries will continue to be permanently reinvested and may not be readily available to meet domestic cash requirements.

To the extent our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds to continue the development and deployment of our technologies, or to supplement our position through strategic acquisitions. There can be no assurance that debt or equity funds will be available on favorable terms, if at all. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of those securities could result in dilution to our stockholders. Moreover, incurring debt financing could result in a substantial portion of our operating cash flow being dedicated to the payment of principal and interest on such indebtedness, could render us more vulnerable to competitive pressures and economic downturns and could impose restrictions on our operations. If adequate funds are not available, we may be required to curtail operations significantly or to obtain funds through entering into agreements on unattractive terms.

Contractual Obligations

As of December 31, 2018, we had approximately $39.6 million in non-cancellable obligations for the next 12 months. These obligations are included in our estimated cash usage during 2019. The following table reflects our

total current non-cancellable obligations by period as of December 31, 2018 (in thousands):

	Payment Due By Period				
Contractual Obligations	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Non-cancellable rental obligations	$28,671	$6,314	$11,641	$7,903	$2,813
Non-cancellable purchase obligations [1]	39,558	33,814	5,744	—	—
Capital lease obligations	65	65	—	—	—
Minimum royalty commitments [2]	122	14	28	80	—
Insurance premiums	730	730	—	—	—
Total [3]	$69,146	$40,937	$17,413	$7,983	$2,813

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(1) Purchase obligations predominantly relate to contractual arrangements in the form of purchase orders primarily as a result of normal inventory purchases or minimum payments due resulting when minimum purchase commitments are not met, as well as other operating commitments.
(2) Amounts represent minimum royalties payable on net sales of products incorporating licensed technology and subject to a minimum annual royalty payment.
(3) Due to the uncertainty with respect to the timing of future cash flows associated with Luminex's unrecognized tax benefits at December 31, 2018, Luminex is unable to make reasonably reliable estimates of the timing of cash settlement with the respective taxing authority. Therefore,$9.7 million of unrecognized tax benefits have been excluded from the contractual obligations table above. See Note 11 to the Consolidated Financial Statements for a discussion on income taxes.

Inflation

We do not believe that inflation has had a direct adverse effect on our operations to date. However, a substantial increase in product and manufacturing costs and personnel related expenses could have an adverse impact on our results of operations in the event these expenses increase at a faster pace than we can increase our system, consumable and royalty revenue rates.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued a new standard on revenue recognition (the Standard) which outlines a single comprehensive model to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The core principle of the revenue model is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted the Standard effective January 1, 2018, using the modified retrospective approach. Under this method, we recorded a cumulative adjustment increasing retained earnings of $10.6 million before related tax impacts or $8.1 million net of related tax impacts. See Note 18, "Revenue Recognition" for additional discussion related to the Company's adoption of the Standard. Under the Standard, estimated royalty revenue will be recorded each quarter on an accrual basis to more closely coincide with the timing of the end user sale by the strategic partner; with reconciliation made upon submission of the royalty report by the partner indicating actual royalties owed in the following quarter. In addition, we began recording the portion of reagent rental revenue associated with the recovery of the cost of providing the system and other hardware in reagent rental agreements as system revenue rather than assay revenue effective January 1, 2018. This change has not and is not expected to have any impact on top line revenue and we do not anticipate any material effects to our revenue categorization.

In January 2016, the FASB issued guidance that amends various aspects of the recognition, measurement, presentation, and disclosure for financial instruments. This guidance was effective for annual reporting periods, and interim periods within those years beginning after December 15, 2017. We adopted this standard during the quarter ended March 31, 2018. The adoption of this new standard resulted in a change to our accounting policy; however, adoption did not have a material impact on our consolidated financial position or results of operations.

In August 2016, the FASB issued specific guidance on eight cash flow classification issues that are not currently addressed by current U.S. GAAP and thereby reduce the current diversity in practice. This guidance is effective for annual periods beginning after December 15, 2017. We adopted this standard during the quarter ended March 31, 2018, and its adoption did not have a material impact on our consolidated financial statements.

In October 2016, the FASB issued guidance on income taxes which requires companies to recognize the income tax effects of intercompany sales and transfers of assets, other than inventory, in the statement of comprehensive income

as income tax expense (or benefit) in the period in which the transfers occur. The new standard became effective for the Company on January 1, 2018. We adopted this new standard using the modified retrospective method through a cumulative-effect adjustment, based on currently enacted tax rates, directly to retained earnings as of the beginning of that date. The adoption of this new standard resulted in a change to our accounting policy; however, adoption did not have a material impact on our consolidated financial position or results of operations.

On January 10, 2018, the FASB issued guidance on the accounting for tax on the global intangible low-taxed income (GILTI) provisions of the Tax Act. The GILTI provisions impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. Effective January 1, 2018, we recognize the tax on GILTI as a period expense in the period the tax is incurred. Under this policy, we have not provided deferred taxes related to temporary differences that upon their reversal will affect the amount of income subject to GILTI in the period.

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In January 2018, the FASB issued guidance related to reporting comprehensive income, which gives entities the option to reclassify to retained earnings the tax effects resulting from the Tax Act related to items in Additional Other Comprehensive Income (AOCI) that the FASB refers to as having been “stranded” in AOCI. The guidance is effective for annual and interim periods beginning after December 15, 2018, and is applicable to Luminex in fiscal year 2019; however, early adoption is permitted. We do not have any tax effects resulting from the Tax Act that are stranded in AOCI and therefore this guidance has no impact on our consolidated financial statements. We have early adopted this guidance and established the accounting policy for reclassifying to retained earnings any tax effects resulting from the Tax Act that are stranded in AOCI.

In June 2018, the FASB issued guidance which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. For public business entities, the guidance is effective for annual periods beginning after December 15, 2018, and interim periods within those annual periods; however, early adoption is permitted. Although nonemployee directors do not satisfy the definition of employee, under FASB guidance, Luminex’s nonemployee directors acting in their role as members of a board of directors are treated as employees as those directors were elected by the Luminex’s shareholders. Therefore, awards granted to these nonemployee directors for their services as directors already were accounted for as employee awards. We early adopted this guidance, which did not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued guidance that eliminates, adds and modifies certain disclosure requirements for fair value measurements. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but public companies will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The guidance is effective for annual and interim periods beginning after December 15, 2019, but entities are permitted to early adopt either the entire standard or only the provisions that eliminate or modify the requirements. We early adopted this guidance, which did not have a material impact on our consolidated financial statements.

In September 2018, the Securities and Exchange Commission (SEC) issued interpretive guidance relating to previously adopted amendments to certain disclosure requirements, including those related to interim disclosures about changes in stockholders’ equity and non-controlling interests. The guidance extends the annual requirement to disclose (1) changes in stockholders’ equity and (2) the amount of dividends per share for each class of shares (as opposed to common stock only, as previously required) to interim periods. The amendments are effective for all filings made on or after November 5, 2018. However, the interpretive guidelines indicate that the SEC would not object if a filer’s first presentation of the change in stockholders’ equity is included in its 10-Q for the quarter that begins after the effective date of the amendments. We adopted this guidance during the quarter ended September 30, 2018 by including prior year, comparative periods in our Consolidated Statement of Changes in Stockholders’ Equity.

In January 2017, the FASB issued guidance on intangibles, including goodwill, which simplifies how companies calculate goodwill impairments by eliminating Step 2 of the impairment test. The guidance requires companies to compare the fair value of a reporting unit to its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value. The guidance is effective for annual periods beginning after December 15, 2019, and is applicable to Luminex in fiscal year 2020; however, early adoption is permitted. We early adopted this guidance in the fourth quarter of 2018, which did not have a material impact on our consolidated financial statements.

Recent Accounting Pronouncements

In June 2016, the FASB issued guidance on financial instruments and related credit losses. The guidance requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The allowance for

credit losses is a valuation account that is deducted from the amortized cost basis. The statement of comprehensive income reflects the measurement of credit losses for newly recognized financial assets, as well as the expected credit losses during the period. The measurement of expected credit losses is based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. The updated guidance is effective for annual periods beginning after December 15, 2019, and is applicable to Luminex in fiscal 2020. Early adoption is permitted. We do not anticipate that this guidance will have a material impact on our consolidated financial statements.

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In February 2016, the FASB issued guidance requiring lessees to recognize a right-of-use asset and a lease liability on the balance sheet for all leases, with the exception of short-term leases. The effective date of the new guidance is for Luminex's first quarter of fiscal year 2019; however, early adoption is permitted. The FASB has approved an optional, alternative method to adopt the lease standard by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. We adopted the new standard effective January 1, 2019, using the alternative method. With the implementation of the standard, we will recognize right-to-use assets and lease liabilities for operating leases of approximately $25 million. We will not have a cumulative adjustment impacting retained earnings. Adoption of the lease standard will not have a material impact on our consolidated statement of comprehensive income nor on our consolidated cash flows statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk. Our interest income is sensitive to changes in the general level of domestic interest rates, particularly since our investments are in long-term instruments available-for-sale. A 50 basis point fluctuation from average investment returns at December 31, 2018 would yield a less than 0.5% variance in overall investment return, which would not have a material adverse effect on our financial condition.

Foreign Currency Risk. Our international business is subject to risks, including, but not limited to: foreign exchange rate volatility, differing tax structures, unique economic conditions, other regulations and restrictions and changes in political climate. Accordingly, our future results could be materially and adversely impacted by changes in these and other factors.

As of December 31, 2018, as a result of our foreign operations, we have costs, assets and liabilities that are denominated in foreign currencies, primarily Canadian dollars and to a lesser extent the Euro, Renminbi and Yen. For example, some fixed asset purchases and certain expenses are denominated in Canadian dollars while sales of products are primarily denominated in U.S. dollars. All transactions in our Netherlands and Japanese subsidiaries are denominated in Euros and Yen, respectively. All transactions, with the exception of our initial capital investment, in our Chinese subsidiary are denominated in Renminbi. As a consequence, movements in exchange rates could cause our foreign currency denominated expenses to fluctuate as a percentage of net revenue, affecting our profitability and cash flows. A significant majority of our revenues are denominated in U.S. dollars. The impact of foreign exchange on foreign denominated balances will vary in relation to changes between the U.S. dollar, Canadian dollar, Euro, Yen and Renminbi exchange rates. A 10% change in all of these exchange rates in relation to the U.S. dollar would result in an statement of comprehensive income impact of approximately $1.1 million on foreign currency denominated asset and liability balances as of December 31, 2018. As a result of our efforts to expand globally, in the future we will be exposed to additional foreign currency risk in multiple currencies; however, at this time, our exposure to foreign currency fluctuations is not material. We regularly assess the market to determine if additional strategies are appropriate to mitigate future risks.

In addition, the indirect effect of fluctuations in interest rates and foreign currency exchange rates could have a material adverse effect on our business financial condition and results of operations. For example, currency exchange rate fluctuations could affect international demand for our products. In addition, interest rate fluctuations could affect our customers' buying patterns. Furthermore, interest rate and currency exchange rate fluctuations may broadly influence the United States and foreign economies resulting in a material adverse effect on our business, financial condition and results of operations. As a result, we cannot give any assurance as to the effect that future changes in foreign currency rates will have on our consolidated financial position, results of operations or cash flows. Our aggregate foreign currency transaction loss of $487,000 was included in determining our consolidated results for the year ended December 31, 2018.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Luminex Corporation

Opinion on Internal Control over Financial Reporting

We have audited Luminex Corporation's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control- Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Luminex Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

As indicated in the accompanying Management's Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of EMD Millipore Corporation's flow cytometry portfolio, which is included in the 2018 consolidated financial statements of the Company and constituted 3% and 2% of total and net assets, respectively, as of December 31, 2018. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of EMD Millipore Corporation's flow cytometry portfolio.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of comprehensive income, changes in stockholders' equity and cash flows, for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 26, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those

policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Ernst & Young LLP
Austin, Texas
February 26, 2019

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Luminex Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Luminex Corporation (the “Company”) as of December 31, 2018 and 2017, the related consolidated statements of comprehensive income, changes in stockholders' equity and cash flows, for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway
Commission (2013 framework) and our report dated February 26, 2019 expressed an unqualified opinion thereon.

Adoption of ASU No. 2014-09

As discussed in Note 18 to the consolidated financial statements, the Company changed its method for accounting for revenue recognition in 2018 due to the adoption of ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606).

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP
We have served as the Company’s auditor since 1998.
Austin, Texas
February 26, 2019

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LUMINEX CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)

	As of December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$76,441	$127,112
Accounts receivable, net	53,396	40,648
Inventories, net	63,250	49,478
Prepaids and other	9,657	7,403
Total current assets	202,744	224,641
Property and equipment, net	66,288	58,258
Intangible assets, net	105,148	75,985
Deferred income taxes	21,470	37,552
Goodwill	118,127	85,481
Other	11,398	8,599
Total assets	$525,175	$490,516
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$14,504	$14,537
Accrued liabilities	26,772	25,990
Deferred revenue	10,099	4,721
Total current liabilities	51,375	45,248
Deferred revenue	1,079	1,498
Other	5,065	5,863
Total liabilities	57,519	52,609
Stockholders' equity:		
Common stock, $.001 par value, 200,000,000 shares authorized; issued and outstanding: 43,899,210 shares at December 31, 2018; 43,404,493 shares at December 31, 2017	44	43
Preferred stock, $.001 par value, 5,000,000 shares authorized; no shares issued and outstanding	—	—
Additional paid-in capital	365,349	350,834
Accumulated other comprehensive loss	(1,127)	(625)
Retained earnings	103,390	87,655
Total stockholders' equity	467,656	437,907
Total liabilities and stockholders' equity	$525,175	$490,516

See the accompanying notes which are an integral part of these
Consolidated Financial Statements.

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LUMINEX CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in thousands, except per share amounts)

	Year Ended December 31,		
	2018	2017	2016
Revenue	$315,818	$306,571	$270,639
Cost of revenue	120,327	107,525	90,984
Gross profit	195,491	199,046	179,655
Operating expenses:			
Research and development	47,164	45,717	48,659
Selling, general and administrative	111,816	107,322	99,511
Amortization of acquired intangible assets	8,665	8,854	8,218
Restructuring costs	—	—	2,281
Total operating expenses	167,645	161,893	158,669
Income from operations	27,846	37,153	20,986
Other income (expense), net	465	(4)	129
Debt prepayment penalty	—	—	(1,500)
Income before income taxes	28,311	37,149	19,615
Income tax expense	(9,803)	(7,726)	(5,801)
Net income	$18,508	$29,423	$13,814
Net income attributable to common stock holders			
Basic	$18,196	$28,894	$13,814
Diluted	18,197	28,894	13,814
Net income per share attributable to common stock holders			
Basic	$0.42	$0.67	$0.32
Diluted	$0.41	$0.67	$0.32
Weighted-average shares used in computing net income per share			
Basic	43,727	43,173	42,584
Diluted	44,291	43,300	43,013
Dividends declared per share	$0.24	$0.24	$—
Other comprehensive income:			
Foreign currency translation adjustments	(502)	1,067	(434)
Unrealized gain on available-for-sale securities, net of tax	—	—	38
Other comprehensive income (loss)	(502)	1,067	(396)
Comprehensive income	$18,006	$30,490	$13,418

See the accompanying notes which are an integral part of these Consolidated Financial Statements.

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LUMINEX CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net income	$18,508	$29,423	$13,814
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	23,674	22,641	20,131
Stock-based compensation	12,226	12,478	11,821
Deferred income tax expense	8,159	6,383	3,626
Loss on sale or disposal of assets	730	964	265
Other	(1,369)	1,531	(1,378)
Changes in operating assets and liabilities:			
Accounts receivable, net	(1,569)	(8,265)	1,136
Inventories, net	(6,827)	(8,668)	(5,484)
Other assets	(3,319)	(83)	1,811
Accounts payable	4	4,469	3,460
Accrued liabilities	103	(2,657)	198
Deferred revenue	579	(785)	281
Net cash provided by operating activities	50,899	57,431	49,681
Cash flows from investing activities:			
Sales and maturities of available-for-sale maturities	—	—	19,491
Purchase of property and equipment	(21,292)	(14,635)	(13,130)
Business acquisition consideration, net of cash acquired	(65,381)	—	(68,098)
Issuance of note receivable	(1,000)	(1,400)	—
Purchase of cost method investment	(1,782)	(1,000)	(1,000)
Proceeds from sale of assets and investments	2	62	45
Acquired technology rights	(4,000)	(140)	(200)
Net cash used in investing activities	(93,453)	(17,113)	(62,892)
Cash flows from financing activities:			
Payments on debt	—	—	(25,000)
Proceeds from issuance of common stock	4,570	4,305	5,089
Shares surrendered for tax withholding	(2,312)	(2,350)	(1,719)
Dividends paid	(10,654)	(7,930)	—
Net cash used in financing activities	(8,396)	(5,975)	(21,630)
Effect of foreign currency exchange rate on cash	279	(683)	(253)
Change in cash and cash equivalents	(50,671)	33,660	(35,094)
Cash and cash equivalents, beginning of period	127,112	93,452	128,546
Cash and cash equivalents, end of period	$76,441	$127,112	$93,452

See the accompanying notes which are an integral part of these
Consolidated Financial Statements.

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LUMINEX CORPORATION
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive (Loss)	Retained Earnings	Total Stockholders' Equity
Balance at December 31, 2015	42,314,581	$ 42	$321,657	$ (1,296)	$48,133	$ 368,536
Exercise of stock options	178,111	—	3,303	—	—	3,303
Issuances of restricted stock, net of shares withheld for taxes	228,480	—	(1,718)	—	—	(1,718)
Stock compensation	—	—	11,776	—	—	11,776
Issuance of common shares under ESPP	81,308	—	1,413	—	—	1,413
Net income	—	—	—	—	13,814	13,814
Stock Comp ASU Tax Entry	—	—	—	—	6,951	6,951
Foreign currency translation adjustments	—	—	—	(434)	—	(434)
Other	—	—	—	38	—	38
Balance at December 31, 2016	42,802,480	$ 42	$336,431	$ (1,692)	$68,898	$ 403,679
Exercise of stock options	163,579	—	2,684	—	—	2,684
Issuances of restricted stock, net of shares withheld for taxes	345,978	1	(2,350)	—	—	(2,349)
Stock compensation	—	—	12,409	—	—	12,409
Issuance of common shares under ESPP	92,456	—	1,591	—	—	1,591
Net income	—	—	—	—	29,423	29,423
Foreign currency translation adjustments	—	—	—	1,067	—	1,067
Dividends	—	—	69	—	(10,666)	(10,597)
Balance at December 31, 2017	43,404,493	$ 43	$350,834	$ (625)	$87,655	$ 437,907
Exercise of stock options	157,754	—	2,814	—	—	2,814
Issuances of restricted stock, net of shares withheld for taxes	253,152	1	(2,312)	—	—	(2,311)
Stock compensation	—	—	12,187	—	—	12,187
Issuance of common shares under ESPP	83,811	—	1,740	—	—	1,740
Net income	—	—	—	—	18,508	18,508
Foreign currency translation adjustments	—	—	—	(502)	—	(502)
Dividends	—	—	86	—	(10,796)	(10,710)
Other	—	—	—	—	8,023	8,023
Balance at December 31, 2018	43,899,210	$ 44	$365,349	$ (1,127)	$103,390	$ 467,656

See the accompanying notes which are an integral part of these Consolidated Financial Statements.

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LUMINEX CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Luminex Corporation, the "Company" or "Luminex," develops, manufactures and sells proprietary biological testing technologies and products with applications throughout the life sciences industries, including diagnostics, pharmaceutical and research. These industries depend on a broad range of tests, called assays, to perform diagnostic testing and conduct life science research. The Company established a position in several segments of the life sciences industries by developing and delivering products that satisfy a variety of customer needs in specific market segments, including multiplexing, accuracy, precision, sensitivity, specificity, reduction of labor and ability to test for proteins and nucleic acids. These needs are addressed by the Company's proprietary technologies.

Multiplexing, the foundation of the Company, allows the end user in a laboratory to generate multiple laboratory results from a single sample with a single assay. This is important because the Company's end user customers, which include laboratory professionals performing discovery and research and clinical laboratories performing tests on patients as ordered by physicians and other laboratories, have a fundamental need to perform high quality testing as efficiently as possible. Until the availability of multiplexing technology, the laboratory professional had to perform one assay at a time in a sequential manner, and if additional testing was required on a sample, a second assay would be performed to generate the second result, and so on until all the necessary tests were performed.

The Company primarily serves the life sciences industries by marketing products, including our specific testing equipment and assays, to various types of testing laboratories. The Company has a large base of installed systems that has grown primarily from the following:

- placements made by customers within the Company's Licensed Technologies Group (LTG), in which customers either:
  - license the Company's xMAP technology and develop products that incorporate the Company's xMAP technology into products that they then sell to end users, or
  - purchase the Company's proprietary xMAP laboratory instrumentation and the Company's proprietary xMAP microspheres and sell xMAP-based assay products and/or xMAP-based testing services, which run on the xMAP instrumentation, and pay a royalty to the Company;
- a direct sales force that focuses on the sale of molecular diagnostic assays that run on the Company's systems.

As of December 31, 2018, the Company had 74 strategic partners, 50 of which have released commercialized reagent-based products utilizing the Company's technology. Luminex and these partners have sold approximately 15,979 xMAP-based instruments in laboratories worldwide as of December 31, 2018, some of which may be retired or otherwise not in use. The Company's remaining partners are in various stages of development and commercialization of products incorporating the Company's technology.

A primary focus for the Company's growth is the development and sale of molecular diagnostic assays utilizing the Company's proprietary MultiCode® and VERIGENE technologies for use on the Company's installed base of systems. The Company utilizes a direct sales model for sales of these products, which is intended to take advantage of the Company's increasing installed base of instruments. Luminex's assays are primarily focused on multiplexed applications for the human molecular clinical diagnostics market. Luminex's assays are currently focused on three segments of the molecular diagnostic testing market: infectious disease, personalized medicine and human genetics.

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Luminex's acquisition of EMD Millipore Corporation's flow cytometry portfolio (Flow Cytometry), completed on December 31, 2018, enhanced the Company's existing offering of flow-based detection systems, while simultaneously expanding its direct interactions with researchers conducting cellular analysis. These flow cytometers and cellular analysis instruments give customers instant access to all facets of cellular phenotypes and morphology. This newly acquired flow cytometry portfolio includes Amnis, a family of imaging flow cytometry products for cell-based analysis, including the highly customizable CellStream, and the FlowSight and ImageStream Imaging Flow Cytometers with quantitative, microscopy imaging, as well as the Guava portfolio of products, high-performance systems based on microcapillary technologies including the Muse Cell Analyzer, which provides miniaturized systems for quick cell counts, viability, and basic cell health analyses, and the Guava easyCyte System, a versatile benchtop platform for additional, multi-dimensional cell health assessments. The results of operations for the acquisition will be included in Luminex's consolidated financial statements beginning January 1, 2019.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany transactions and balances have been eliminated upon consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual amounts and results could differ from those estimates, and such differences could be material to the financial statements.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash deposits and highly liquid investments with original maturities of three months or less when purchased.

Investments

The Company determines the appropriate classification of its investments in equity securities at the time of purchase and reevaluates such determinations at each balance sheet date. Marketable securities that are bought and held principally for the purpose of selling them in the near-term are classified as trading securities and are reported at fair value, with unrealized gains and losses recognized in earnings. Held-to-maturity securities are stated at amortized cost, which approximates fair value of these investments. Marketable equity securities not classified as held-to-maturity or as trading are classified as available-for-sale, and are carried at fair market value, with the unrealized gains and losses included in the determination of comprehensive income and reported in stockholders' equity. Marketable securities are recorded as either short-term or long-term on the balance sheet based on contractual maturity date. The fair value of all securities is determined by obtaining non-binding market prices from the Company's third-party portfolio managers on the last day of the quarter, whose sources may use quoted prices in active markets for identical assets or inputs other than quoted prices that are observable either directly or indirectly in determining fair value. Declines in fair value below the Company's carrying value deemed to be other than temporary are charged against net earnings.

Fair Value of Financial Instruments

The fair values of financial instruments are determined by obtaining non-binding market prices from the Company's third-party portfolio managers on the last day of the quarter, whose sources may use quoted prices in active markets for identical assets or inputs other than quoted prices that are observable either directly or indirectly in determining

fair value. The Company's financial instruments include cash and cash equivalents, short-term investments, accounts receivable, cost-method investments, long-term investments, accounts payable and accrued liabilities. The fair values of these financial instruments were not materially different from their carrying or contract values at December 31, 2018 and 2017. See Note 6 for further details concerning fair value measurements.

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Supplemental Cash Flow Statement Information (in thousands)

	Year Ended December 31,		
	2018	2017	2016
Cash paid during the period for taxes	$2,214	$1,393	$385
Cash (received) paid during the period for interest and penalties	17	57	(3)
Cash paid during the period for Nanosphere debt interest	—	—	391
Cash paid during the period for Nanosphere debt prepayment penalty	—	—	1,500
Effect of acquisitions:			
Fair value of tangible assets acquired	13,262	—	34,372
Liabilities assumed	(5,082)	—	(25,391)
Cost in excess of fair value of assets acquired	32,647	—	35,862
Acquired identifiable intangible assets	26,797	—	27,595
Deferred tax assets (liabilities), net	(4,433)	—	6,989
In-process research and development	6,703	—	12,982
Total purchase price	69,894	—	92,409
Less cash and cash equivalents acquired	4,513	—	24,311
Net cash paid for business acquisition	$65,381	$—	$68,098

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of short-term and long-term investments and trade receivables. The Company’s short-term investments consist of investments in high credit quality financial institutions, non-government sponsored debt securities and corporate issuers.

The Company provides credit, in the normal course of business, to a number of its customers geographically dispersed primarily throughout the U.S. The Company attempts to limit its credit risk by performing ongoing credit evaluations of its customers and maintaining adequate allowances for potential credit losses, but the Company does not require collateral.

LabCorp accounted for 15%, 20% and 20% of our total revenues in 2018, 2017 and 2016, respectively. Thermo Fisher Scientific Inc. accounted for 14%, 15% and 13% of our total revenues in 2018, 2017 and 2016, respectively. No other customer accounted for more than 10% of our total revenues in 2018, 2017 or 2016.

Inventories

Inventories, consisting primarily of raw materials and purchased components, are stated at the lower of cost or net realizable value, with cost determined according to the standard cost method, which approximates the first-in, first-out method. Net realizable value is defined as the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. As a developer and manufacturer of high technology medical equipment, the Company may be exposed to a number of economic and industry factors that could result in portions of inventory becoming either obsolete or in excess of anticipated usage. These factors include, but are not limited to, technological changes in the Company’s markets, ability to meet changing customer requirements, competitive pressures on products and prices, and reliability and replacement of and the availability of key components from suppliers. The Company’s policy is to establish inventory reserves when conditions exist that suggest that inventory may be in excess of anticipated demand or is obsolete based upon the Company’s assumptions about future demand for products and market conditions. The Company regularly evaluates the ability to realize the value of inventory based on a combination of factors including the following: historical usage rates, forecasted sales or usage, product expiration or end of life dates, estimated current and future market values and new product

introductions. Assumptions used in determining the Company's estimates of future product demand may prove to be incorrect, in which case the provision required for excess and obsolete inventory would have to be adjusted. If inventory is determined to be overvalued, excess or obsolete, the Company would be required to record impairment charges within cost of goods sold at the time of such determination. Although considerable effort is made to ensure the accuracy of forecasts of future product demand, any significant unanticipated changes in demand or expected usage could have a significant negative impact on the value of inventory and the Company's operating results. When recorded, reserves are intended to reduce the carrying value of inventory to its net realizable value.

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Property and Equipment

Property and equipment are carried at cost less accumulated amounts for amortization and depreciation. Property and equipment are typically amortized or depreciated on a straight-line basis over the useful lives of the assets, which typically range from two to seven years. Leasehold improvements and equipment under capital leases are amortized on a straight-line basis over the shorter of the remaining term of the lease or the estimated useful life of the improvements and equipment. The Company classifies the carrying value of Luminex's xMAP, ARIES® and VERIGENE Systems placed within the reagent rental program and the instruments on loan to customers in property and equipment as "Assets on loan/rental."

Goodwill and Other Intangible Assets

Goodwill represents the excess of the cost over the fair value of the assets of the acquired business. In accordance with Accounting Standards Codification (ASC) 350 "Goodwill and Other" (ASC 350), goodwill is reviewed for impairment at least annually at the beginning of the fourth quarter, or more frequently if impairment indicators arise, tested at our sole reporting unit level. Events or circumstances that could trigger an impairment test include, but are not limited to, a significant adverse change in the business climate, significant changes in our use of the acquired assets, significant negative industry or economic trends, significant under-performance relative to operating performance indicators and significant changes in competition. The Company determined that no triggering events occurred during the year ended December 31, 2018. In 2018 and 2017, the Company estimated the fair value of the reporting unit using a fair-value-based approach based on the market capitalization. Determining the fair value of goodwill is subjective in nature and often involves the use of estimates and assumptions including, without limitation, use of estimates of future prices and volumes for the Company's products, capital needs, economic trends and other factors which are inherently difficult to forecast. The Company's annual test did not result in an impairment charge in 2018, as the estimated fair value of the reporting unit continued to exceed the carrying value by a significant enough amount such that any reasonably likely change in the assumptions used in the analysis would not cause the carrying value to exceed the estimated fair value for the reporting unit. No goodwill impairments were recorded in 2018, 2017 or 2016.

Intangible assets are amortized on a straight-line basis over their respective estimated useful lives ranging from 9 to 15 years. Any in-process research and development will be an indefinite-lived intangible asset until completion or abandonment, at which point it will be accounted for as a finite-lived intangible asset or written off if abandoned.

Impairment of Long-Lived Assets

Long-lived assets held and used by the Company are reviewed for impairment whenever events or changes in circumstances indicate that their net book value may not be recoverable. When such factors and circumstances exist, the Company compares the projected undiscounted future cash flows associated with the related asset or group of assets over their estimated useful lives against their respective carrying amounts. Impairment, if any, is based on the excess of the carrying amount over the fair value of those assets and is recorded in the period in which the determination was made.

Revenue Recognition and Allowance for Doubtful Accounts

Performance Obligations: Revenue is generated primarily from the sale of the Company's products and related services, which are primarily support and maintenance services on the Company's systems. The Company recognizes product revenue when the customer obtains control of the Company's product, which typically occurs upon shipment or delivery to the customer depending upon the shipping terms. We treat shipping and handling costs performed after a customer obtains control of the good as a fulfillment cost. Our customers do not typically have any contractual rights

of return outside of our warranty provisions. The Company has allowed few returns to date and believes that returns of its products will be minimal in the future.

Royalties: For arrangements that include sales-based royalties, including minimum payments, the Company recognizes revenue at the later of: (i) when the related sales occur, or (ii) when the performance obligation, to which some or all of the royalty has been allocated, has been satisfied. This is a change from how the Company has historically treated royalty payments, by recognizing royalty revenue when our strategic partners reported the end-user sales to the Company, and is primarily the basis for our cumulative adjustment, made as of January 1, 2018, to retained earnings of $10.6 million before related tax impacts or $8.1 million net of related tax impacts. Royalty payments are typically received when our strategic partners report the end-user sales to the Company.

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Reagent Rentals: The Company provides systems and certain other hardware to customers through reagent rental agreements, under which the customers commit to purchasing minimum quantities of assays at a stated price over a defined contract term, which is normally two to three years. Instead of rental payments, the Company recovers the cost of providing the system and other hardware in the amount charged for assays. Revenue is recognized over the defined contract term as assays are shipped. The depreciation costs associated with the system and other hardware are charged to cost of sales on a straight-line basis over the estimated life of the system. The costs to maintain these instruments in the field are charged to cost of sales as incurred. Under the guidance, the Company has reclassified the portion of reagent rental revenue associated with the recovery of the cost of providing the system and other hardware in reagent rental agreements from assay revenue to system revenue effective January 1, 2018. This change will not have any impact on top line revenue and the Company does not anticipate any material effects to its revenue categorization.

Warranties: The Company provides a limited, assurance-type warranty, typically for twelve months from installation for the systems sold to end customers and fifteen months for the systems sold to partners. The Company accrues for the estimated cost of initial product warranties at the time revenue is recognized. While the Company engages in product quality programs and processes, the Company's warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. While the Company believes that adequate reserve has been made in the consolidated financial statements for product warranties, should actual product failure rates, material usage or service delivery costs differ from the Company's estimates, revisions to the estimated warranty liability would be required. Warranty expenses are evaluated and adjusted periodically.

License Revenues: The Company enters into out-licensing agreements, under which it licenses certain rights to its technology to third parties. These licenses are typically not distinct, as the customer cannot benefit from the license on its own, and do not have significant standalone functionality, but represent single performance obligations together with the sales of our consumables, systems and assays. The terms of these arrangements typically include payment to the Company of non-refundable, up-front license fees and can extend up to twenty years. Each of these payments results in license revenues which are recognized ratably over time and are included in other revenues, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues. Deferred revenues related to these out-licensing agreements are shown in contract liabilities in Note 18, "Revenue Recognition".

Service Agreements: Revenue from extended service agreements is deferred when payment is received in advance of the performance obligation being satisfied or completed. Luminex provides an integrated service of maintenance and related activities for equipment sold to customers, where the nature of the overall promise is to provide a stand-ready service. As such, the performance obligation is recognized as a series of distinct service periods and the service revenue is recognized ratably over the term of each agreement. The extended service agreements typically range from one to four years and payment is typically received up-front.

Reserves for Variable Consideration: Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from discounts and any other allowances that are offered within contracts between the Company and its customers relating to the Company's sales of its products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable. Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as the Company's historical experience, current contractual requirements, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of each contract. The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual

amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period when such variances become known.

Allowance for Doubtful Accounts: The Company continuously monitors collections and payments from its customers and maintains allowances for doubtful accounts based upon its historical experience and any specific customer collection issues that have been identified. While such credit losses have historically been within the Company's expectations, there can be no assurance that the Company will continue to experience the same level of credit losses that it has in the past. A significant change in the liquidity or financial position of any one of the Company's significant customers, or a deterioration in the economic environment in general, could have a material adverse impact on the collectability of the Company's accounts receivable and its future operating results, including a reduction in future revenues and additional allowances for doubtful accounts.

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Product-Related Expenses

The Company provides for the estimated cost of initial product warranties at the time revenue is recognized. While the Company engages in product quality programs and processes, the Company's warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from the Company's estimates, revisions to the estimated warranty liability would be required. Shipping and handling costs associated with product sales are included in cost of sales. Advertising costs are charged to operations as incurred. The Company does not have any direct-response advertising. Advertising expenses, which include trade shows and conventions, were approximately $2.8 million, $2.4 million and $2.2 million for 2018, 2017 and 2016, respectively, and were included in selling, general and administrative expense in the Consolidated Statements of Comprehensive Income.

Research and Development Costs

Research and development costs are expensed in the period incurred. Nonrefundable advance payments for research and development activities for materials, equipment, facilities and purchased intangible assets that have an alternative future use are deferred and capitalized. In addition, the Company capitalizes certain internally developed products used for evaluation during development projects that also have alternative future uses. These internally developed assets are generally depreciated on a straight-line basis over the useful life of the assets, which range from one to five years.

Foreign Currency Translation

The financial statements of the Company's foreign subsidiaries are translated in accordance with ASC 830, "Foreign Currency Matters." The reporting currency for the Company is the U.S. dollar. With the exception of its Canadian subsidiary, whose functional currency is the U.S. dollar, the functional currency of the Company's foreign subsidiaries is their local currency. Accordingly, assets and liabilities of these subsidiaries are translated at the exchange rate in effect at each balance sheet date. Before translation, the Company re-measures foreign currency denominated assets and liabilities, including inter-company accounts receivable and payable, into the functional currency of the respective entity, resulting in unrealized gains or losses recorded in selling, general and administrative expenses in the Consolidated Statement of Comprehensive Income. Revenues and expenses are translated using average exchange rates during the respective period. Foreign currency translation adjustments are accumulated as a component of other comprehensive income as a separate component of stockholders' equity. Gains and losses arising from transactions denominated in foreign currencies are included in selling, general and administrative expenses in the Consolidated Statement of Comprehensive Income and to date have not been material.

Incentive Compensation

Management incentive plans are tied to various financial and non-financial performance metrics. Bonus accruals made throughout the year related to the various incentive plans are based on management's best estimate of the achievement of the specific metrics. Adjustments to the accruals are made on a quarterly basis as forecasts of performance are updated. At year-end, the accruals are adjusted to reflect the actual results achieved.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax balances are adjusted to

reflect tax rates based on currently enacted tax laws, which will be in effect in the years in which the temporary differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period of the enactment date. A valuation allowance is recorded to reduce the carrying amounts of deferred tax assets unless it is more likely than not that those assets will be realized.

The Company accounts for uncertain tax positions in accordance with ASC 740, “Income Taxes”, which clarifies the accounting for uncertainty in tax positions. These provisions require recognition of the impact of a tax position in the Company’s financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected as a component of income tax expense.

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Earnings Per Share

Basic net income per share is computed by dividing the net income for the period by the weighted average number of common shares outstanding during the period. Diluted net income per share is computed by dividing the net income for the period by the weighted average number of common shares and potential common shares from outstanding stock options, restricted stock units (RSUs) and contingently issuable shares resulting from an award subject to performance or market conditions determined by applying the treasury stock method. In periods with a net loss, potentially dilutive securities composed of incremental common shares issuable upon the exercise of stock options and warrants, and common shares issuable on conversion of preferred stock, would be excluded from historical diluted loss per share because of their anti-dilutive effect.

Stock-Based Compensation

The Company accounts for stock-based employee compensation plans under the fair value recognition and measurement provisions of ASC 718 “Stock Compensation” (ASC 718). ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options, restricted stock units and shares issued under the Company’s employee stock purchase plan. Pursuant to ASC 718, stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense over the requisite service period.

NOTE 2 — BUSINESS COMBINATIONS

On December 31, 2018, the Company completed its acquisition (the Acquisition) of EMD Millipore Corporation’s flow cytometry portfolio for $75 million, consisting of approximately $69.9 million paid under a Share and Asset Purchase Agreement (the Purchase Agreement) and approximately $5.1 million in committed inventory purchases, both of which are subject to adjustment. The Company financed the acquisition with cash on hand. Luminex acquired 100% of the shares and equity of Amnis Corporation, a Washington Corporation (“Amnis”), a wholly owned subsidiary of EMD Millipore Corporation, a Massachusetts corporation (itself an affiliate of Merck KgaA), and certain other assets owned by other affiliates of Merck KgaA (“MilliporeSigma”).

The Acquisition expands Luminex’s existing offering of flow-based detection systems, which is centered around its innovative xMAP® multiplexing technology, with more than 15,000 xMAP systems sold worldwide. MilliporeSigma’s flow cytometry portfolio includes Amnis, a family of imaging flow cytometry products for cell-based analysis, as well as their Guava and Muse portfolio of products, which are economical systems based on microcapillary technologies. The purchase price was in excess of the fair value of the net assets acquired and, as a result, the Company recorded goodwill. A portion of the goodwill is deductible for tax purposes. The Company recorded approximately $2.7 million of acquisition-related costs during fiscal 2018. The impact of the Acquisition on our liquidity is more fully described under “Liquidity and Capital Resources.”

The following table summarizes the preliminary estimated fair values of assets acquired and liabilities assumed in connection with the Acquisition at December 31, 2018 (in thousands):

Net tangible assets assumed as of December 31, 2018	$8,181
Intangible assets subject to amortization	33,500
Deferred tax liabilities	(4,433)
Goodwill	32,646
Total purchase price	$69,894

The Company is in the process of obtaining third-party valuations of certain intangible assets, performing a reconciliation of the assets and liabilities purchased with EMD Millipore Corporation and finalizing the calculations of the deferred tax assets and liabilities related to the Acquisition; thus the provisional measurement of net tangible assets assumed, intangible assets, deferred tax assets and liabilities and goodwill are subject to change. If information that existed prior to December 31, 2018 becomes available which would indicate adjustments are required to the purchase price allocation, such adjustments will be included in the purchase price allocations retrospectively through revisions to the net tangible assets assumed, fair values of the intangible assets, deferred tax assets and liabilities and resulting goodwill recorded.

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Unaudited Pro forma Financial Information

The fourth quarter 2018 results of operations of business acquired in connection with the Acquisition are not included in our consolidated statements of comprehensive income for the three and twelve months ended December 31, 2018 as the Acquisition closed on December 31, 2018, but the financial position of the Acquisition is included in our consolidated balance sheet as of December 31, 2018. The unaudited pro forma financial information set forth below assumes that the Acquisition had been completed at the beginning of 2017 and includes the effect of estimated amortization of acquired identifiable intangible assets, removal of Acquisition costs and the impact of preliminary estimated purchase accounting adjustments, tax and inventory valuation adjustments. This unaudited pro forma financial information is presented for informational purposes only and is not necessarily indicative of the results of operations that actually would have resulted had the Acquisition been completed at the beginning of the periods presented. In addition, the unaudited pro forma financial information is not intended to be a projection of future results and does not reflect any operating efficiencies or cost savings that might be achievable.

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
	(in thousands)		(in thousands)	
Revenue	$92,155	$91,705	$355,042	$358,885
Income from operations	1,116	9,823	26,121	36,606
Net income (loss)	(2,200)	(2,533)	17,359	29,077
Earnings per share:				
Basic	(0.05)	(0.06)	0.39	0.66
Diluted	(0.05)	(0.06)	0.38	0.66

NOTE 3 — INVESTMENTS AND OTHER ASSETS

Marketable Securities

The Company determines the appropriate classification of any investments in debt and equity securities at the time of purchase and re-evaluates such determinations at each balance sheet date. As of December 31, 2018, the Company had no short or long-term investments, since those funds were used to pay for acquisitions.

Available-for-sale securities consisted of the following as of December 31, 2018 (in thousands):

	Amortized Cost	Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	Estimated Fair Value
Current:				
Money Market funds	$ 704	$ —	$ —	$ 704
Total current securities	704	—	—	704
Noncurrent:				
Total noncurrent securities	—	—	—	—
Total available-for-sale securities	$ 704	$ —	$ —	$ 704

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Available-for-sale securities consisted of the following as of December 31, 2017 (in thousands):

	Amortized Cost	Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	Estimated Fair Value
Current:				
Money Market funds	$ 701	$ —	$ —	$ 701
Total current securities	701	—	—	701
Noncurrent:				
Total noncurrent securities	—	—	—	—
Total available-for-sale securities	$ 701	$ —	$ —	$ 701

There were no proceeds from the sales of available-for-sale securities for the years ended December 31, 2018 and December 31, 2017. Realized gains and losses on sales of investments are determined using the specific identification method and are included in other income (expense) in the Consolidated Statement of Comprehensive Income. There were no available-for-sale debt securities as of December 31, 2018 or December 31, 2017. All of the Company's available-for-sale securities with gross unrealized losses as of December 31, 2018 had been in a loss position for less than 12 months.

Non-Marketable Securities and Other-Than-Temporary Impairment

During the year ended December 31, 2018, the Company made a $1.8 million investment in a private company. Based in the U.S., this minority investment is included at cost in other long-term assets of the Company's Consolidated Balance Sheets. The Company does not have significant influence over the investee since the Company owns less than 20% of the voting equity in the investee. Further, the Company does not participate in policy-making processes or interchange managerial personnel.

During each of the years ended December 31, 2017 and 2016, the Company made a $1.0 million minority interest investment (an aggregate of $2.0 million) in a second private company based in the U.S. that is focused on development of next generation technologies. During the year ended December 31, 2017, the Company also entered into a $1.4 million promissory note with this same private company. The Company loaned an additional $1.0 million to the private company in the year ended December 31, 2018, resulting in a notes receivable balance of $2.4 million as of June 30, 2018, payable at the annual interest rate of 1.95% with a maturity date of 5 years from the date of issuance. In August 2018, the Company exercised its purchase option of the private company and acquired 100% of its capital stock in a non-cash transaction involving (i) the prior investment of $2.0 million being applied to the purchase option, (ii) the forgiveness and application of the $2.4 million note and related interest receivable to the purchase option and (iii) a tax impact of $0.1 million. This acquisition has been accounted for as an asset acquisition rather than a business combination, as substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset, a next generation technology. The Company has recorded the $4.3 million asset acquisition as a defensive, in-process research and development (IP R&D) intangible asset. There were no gains or losses recognized as part of this transaction.

The Company owns a minority interest in another private company based in the U.S. through its investment of $1.0 million in the third quarter of 2012. This minority interest is included at cost in other long-term assets on the Company's Consolidated Balance Sheets as the Company does not have significant influence over the investee, as the Company owns less than 20% of the voting equity and the investee is not publicly traded.

These investments do not have readily determinable fair values. Therefore, the Company has elected the measurement alternative for its minority interests and the investments are recorded at cost, less any impairment, including changes resulting from observable price changes. The Company regularly evaluates the carrying value of its investment for impairment and whether any events or circumstances are identified that would significantly harm the fair value of the investment. The primary indicators the Company utilizes to identify these events and circumstances are the investee's ability to remain in business, such as the investee's liquidity and rate of cash use, and the investee's ability to secure additional funding and the value of that additional funding. In the event a decline in fair value is less than the investment's carrying value, the Company will record an impairment charge in Other Income, net in the Consolidated Statements of Comprehensive Income. As of December 31, 2018, the Company has not recorded any impairment charges related to the investments discussed above.

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As the inputs utilized for the Company's periodic impairment assessment are not based on observable market data, the determination of fair value of its investments is classified within Level 3 of the fair value hierarchy. See Note 6 - Fair Value Measurement to our Condensed Consolidated Financial Statements for further information on the fair value hierarchy and the three classification levels. To determine the fair value of these investments, the Company uses all available financial information related to the entities, including information based on recent or pending third-party equity investments in these entities. In certain instances, an investment's fair value is not estimated as there are no identified events or changes in the circumstances. There have been no unrealized gains or losses related to these level 3 minority interest investments.

Other long-term assets consisted of the following at December 31 (in thousands):

	2018	2017
Purchased technology rights (net of accumulated amortization of $7,633 and $7,012 in 2018 and 2017, respectively)	$6,653	$3,149
Minority interest investments	2,782	3,000
Notes receivable [1]	—	1,400
Other	1,963	1,050
	$11,398	$8,599

[1] In August 2018, the Company exercised its purchase option of the private company for which it held a $2.0 million minority interest
investment, resulting in the prior investment and the related note receivable being applied to the purchase price. As discussed above, this
purchased asset has been recorded as an IP R&D intangible asset.

For the years ended December 31, 2018 and 2017, the Company recognized amortization expense related to the amortization of purchased technology rights of approximately $621,000 and $559,000, respectively. Future amortization expense is estimated to be $647,000 in 2019, $547,000 in 2020, $515,000 in 2021, $497,000 in 2022, $481,000 in 2023 and $3,965,000 thereafter.

NOTE 4 — ACCOUNTS RECEIVABLE AND RESERVES

The Company records an allowance for doubtful accounts based upon a specific review of all outstanding invoices, known collection issues and historical experience. The Company regularly evaluates the collectability of its trade accounts receivables and performs ongoing credit evaluations of its customers and adjusts credit limits based upon payment history and its assessment of the customer's current creditworthiness. These estimates are based on specific facts and circumstances of particular orders, analysis of credit memo data and other known factors. Accounts receivable consisted of the following at December 31 (in thousands):

	2018	2017
Accounts receivable	$54,239	$41,993
Less: Allowance for doubtful accounts	(843)	(1,345)
	$53,396	$40,648

The following table summarizes the changes in the allowance for doubtful accounts (in thousands):

Balance at December 31, 2015	$204
Net increases charged to costs and expenses	320
Write-offs of uncollectible accounts	(105)
Balance at December 31, 2016	$419
Net increases charged to costs and expenses	1,312
Write-offs of uncollectible accounts	(386)
Balance at December 31, 2017	1,345

Net recoveries charged to costs and expenses	(437)
Write-offs of uncollectible accounts	(65)
Balance at December 31, 2018	843

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NOTE 5 — INVENTORIES, NET

Inventories consisted of the following at December 31 (in thousands):

	2018	2017
Parts and supplies	$39,873	$29,266
Work-in-progress	11,847	8,712
Finished goods	11,530	11,500
	$63,250	$49,478

The Company has non-cancellable purchase commitments with certain of its component suppliers in the amount of approximately $39.6 million at December 31, 2018. Should production requirements fall below the level of the Company's commitments, the Company could be required to take delivery of inventory for which it has no immediate need or incur an increased cost per unit going forward.

NOTE 6 — FAIR VALUE MEASUREMENT

ASC 820 "Fair Value Measurement" (ASC 820) defines fair value, establishes a framework for measuring fair value under U.S. GAAP and enhances disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. ASC 820 describes a fair value hierarchy based on the following three levels of inputs that may be used to measure fair value, of which the first two are considered observable and the last unobservable:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company determines the fair value of its investment portfolio assets by obtaining non-binding market prices from its third-party portfolio managers on the last day of the quarter, whose sources may use quoted prices in active markets for identical assets (Level 1 inputs) or inputs other than quoted prices that are observable either directly or indirectly (Level 2 inputs) in determining fair value. There were no transfers between Level 1, Level 2 or Level 3 measurements for the year ended December 31, 2018.

The following table represents the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2018 and 2017 (in thousands):

	Fair Value Measurements as of December 31, 2018 Using			
	Level 1	Level 2	Level 3	Total
Assets:				
Money Market funds	$704	$ —	$—	$704

Minority Interest Investments	$—	$ —	$2,782	$2,782

	Fair Value Measurements as of December 31, 2017 Using			
	Level 1	Level 2	Level 3	Total
Assets:				
Money Market funds	$701	$ —	$—	$701
Minority Interest Investments	$—	$ —	$3,000	$3,000

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NOTE 7 — PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31 (in thousands):

	2018	2017
Laboratory equipment	$58,330	$52,498
Leasehold improvements	39,289	37,155
Computer equipment	3,322	3,174
Purchased software	22,141	22,056
Furniture and fixtures	5,874	5,842
Assets on loan/rental	24,259	15,741
Capital lease equipment	846	962
	154,061	137,428
Less: Accumulated depreciation	(87,773)	(79,170)
	$66,288	$58,258

Depreciation expense was $14.4 million, $13.2 million and $11.5 million for the years ended December 31, 2018, 2017, and 2016, respectively.

NOTE 8 — GOODWILL AND OTHER INTANGIBLE ASSETS

On December 31, 2018, the Company completed the Acquisition. As a result of the Acquisition, the Company recorded approximately $32.6 million of goodwill and $33.5 million of other identifiable intangible assets. The goodwill is derived from expected synergies from combining operations of the Company and the business acquired in connection with the Acquisition. The purchase price allocation is preliminary as the Company’s determination of the fair values of the assets acquired and liabilities assumed is still in progress. The Company’s goodwill is not expected to be deductible for tax purposes. The changes in the carrying amount of goodwill during the period are as follows (in thousands):

	December 31, 2018	December 31, 2017
Balance at beginning of period	$ 85,481	$ 85,481
Flow cytometry acquisition	$ 32,646	$ —
Balance at end of period	$ 118,127	$ 85,481

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The Company's intangible assets are reflected in the table below (in thousands, except weighted average lives):

	Finite-lived			Indefinite-lived	
	Technology, trade secrets and know-how	Customer lists and contracts	Other identifiable intangible assets	IP R&D	Total
2017					
Balance as of December 31, 2016	$81,385	$19,097	$ 5,664	$ 12,982	$119,128
Balance as of December 31, 2017	81,385	19,097	5,664	12,982	119,128
Less: accumulated amortization:					
Accumulated amortization balance as of December 31, 2016	(28,137)	(5,038)	(1,112)	—	(34,287)
Amortization expense	(6,277)	(1,999)	(580)	—	(8,856)
Accumulated amortization balance as of December 31, 2017	(34,414)	(7,037)	(1,692)	—	(43,143)
Net balance as of December 31, 2017	$46,971	$12,060	$ 3,972	$ 12,982	$75,985
Weighted average life (in years)	11	10	10		
2018					
Balance as of December 31, 2017	$81,385	$19,097	$ 5,664	$ 12,982	$119,128
Flow cytometry acquisition	17,084	4,722	4,991	6,703	33,500
Asset acquisition	—	—	—	4,328	4,328
Balance as of December 31, 2018	98,469	23,819	10,655	24,013	156,956
Less: accumulated amortization:					
Accumulated amortization balance as of December 31, 2017	(34,414)	(7,037)	(1,692)	—	(43,143)
Amortization expense	(6,087)	(1,999)	(579)	—	(8,665)
Accumulated amortization balance as of December 31, 2018	(40,501)	(9,036)	(2,271)	—	(51,808)
Net balance as of December 31, 2018	$57,968	$14,783	$ 8,384	$ 24,013	$105,148
Weighted average life (in years)	11	10	10		

As discussed in Note 3 above, in August 2018, the Company exercised its purchase option of a private company and recorded approximately $4.3 million of intangible assets through an asset acquisition. The Company currently has three IP R&D projects. The first relates to the development of the next generation VERIGENE® System, VERIGENE II, on which the Company began clinical trials in May 2018. The Company believes the VERIGENE II will launch commercially in 2019. The second is a defensive IP R&D project related to the Company's next generation xMAP System, the SENSIPLEX, which the Company believes will launch commercially in 2020. The third relates to the development of the next generation Guava System, acquired as part of the Acquisition. The fair value of the Guava Next Gen IP R&D project was determined using the income approach. The discount rate applied to the projected cash flows was 13.0%, which reflects the engineering and technical risks related to the projects. The allocation of the purchase price is preliminary and subject to change, based on the finalization of income tax matters. The Company believes the Guava Next Gen System will launch by the end of 2019. The estimated costs to complete these IP R&D projects are approximately $9.9 million.

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The estimated aggregate amortization expense for the next five fiscal years and thereafter is as follows (in thousands):

2019	$11,345
2020	11,345
2021	10,987
2022	9,740
2022	9,391
Thereafter	28,327
	$81,135
IP R&D	24,013
	$105,148

NOTE 9 — OTHER COMPREHENSIVE (LOSS) INCOME

Comprehensive (loss) income represents a measure of all changes in equity that result from recognized transactions and other economic events other than those resulting from investments by and distributions to shareholders. Other comprehensive (loss) income for the Company includes foreign currency translation adjustments and net unrealized holding gains and losses on available-for-sale investments.

The following table presents the changes in each component of accumulated other comprehensive (loss) income, net of tax (in thousands):

	Foreign Currency Items	Available-for-Sale Investments	Accumulated Other Comprehensive Income (Loss) Items
Balance as of December 31, 2017	$(625)	$—	$(625)
Other comprehensive income	(502)	—	(502)
Net current-period other comprehensive loss	(502)	—	(502)
Balance as of December 31, 2018	$(1,127)	$—	$(1,127)

There are no tax benefits or expenses related to the other comprehensive loss for the twelve months ended December 31, 2018.

NOTE 10 — ACCRUED LIABILITIES

Accrued liabilities consisted of the following as of December 31 (in thousands):

	2018	2017
Compensation and employee benefits	$18,086	$18,218
Income and other taxes	1,014	1,070
Warranty costs	1,901	1,308
Dividends payable	2,703	2,671
Other	3,068	2,723
	$26,772	$25,990

Sales of certain of the Company’s systems are subject to a warranty. System warranties typically extend for a period of twelve months from the date of installation or no more than 15 months from the date of shipment. The Company estimates the amount of warranty claims on sold products that may be incurred based on current and historical data. The actual warranty expense could differ from the estimates made by the Company based on product performance. Warranty expenses are evaluated and adjusted periodically.

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The following table summarizes the changes in the warranty accrual (in thousands):

Accrued warranty costs at December 31, 2015	$553
Warranty services provided	(1,322)
Accrual for warranty costs	1,444
Accrued warranty costs at December 31, 2016	675
Warranty services provided	(2,049)
Accrual for warranty costs	2,682
Accrued warranty costs at December 31, 2017	1,308
Warranty services provided	(2,159)
Accrual for warranty costs	2,752
Accrued warranty costs at December 31, 2018	$1,901

NOTE 11 — INCOME TAXES

The components of income before income taxes for the years ended December 31 are as follows (in thousands):

	2018	2017	2016
Domestic	$7,242	$18,436	$2,281
Foreign	21,069	18,713	17,334
Total	$28,311	$37,149	$19,615

The components of the (benefit) provision for income taxes attributable to continuing operations for the years ended December 31 are as follows (in thousands):

	2018	2017	2016
Current:			
Federal	$(3,318)	$3,149	$1,545
Foreign	515	295	204
State	600	883	449
Total current	$(2,203)	$4,327	$2,198
Deferred:			
Federal	6,351	14,970	(215)
Foreign	5,271	(9,267)	3,813
State	384	(2,304)	5
Total deferred	12,006	3,399	3,603
Total provision for income taxes	$9,803	$7,726	$5,801

The Tax Cuts and Jobs Act (the Tax Act) was enacted on December 22, 2017 making significant reforms to the Internal Revenue Code. The reforms include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, transition of U.S. international taxation from a worldwide tax system to a territorial system, and a mandatory one-time transition tax on the deemed repatriation of cumulative foreign earnings as of December 31, 2017. On December 22, 2017, Staff Accounting Bulletin No. 118 (SAB 118) was issued to address the implication of US GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act and provides a one-year measurement period to complete the accounting required under ASC 740.

We applied the guidance in SAB 118 when accounting for the enactment-date effects of the Tax Act in 2017 and throughout 2018. At December 31, 2017, we had not completed our accounting for all the enactment-date income tax effects of the Tax Act under ASC 740, Income Taxes. The Company finalized its provisional amounts in the fourth quarter of 2018 for the following aspects: remeasurement of deferred tax assets and liabilities, one-time transition tax,

and other deferred tax impacts.

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Deferred tax assets and liabilities

As of December 31, 2017, we remeasured certain deferred tax assets and liabilities based on the rates at which they were expected to reverse in the future (which was generally 21%), by recording a provisional expense of $2.7 million. Upon further analysis of certain aspects of the Tax Act and refinement of our calculations during the twelve months ended December 31, 2018, we reduced our provisional expense by $74,000, which is included as a component of income tax expense from continuing operations.

One-time transition tax

The one-time transition tax is based on the Company's total post-1986 earnings and profits (E&P), which the Company had deferred from U.S. income taxes under previous U.S. law. In the fourth quarter of 2017, we recorded a provisional amount for our one-time transition tax liability for each of our foreign subsidiaries, resulting in a transition tax liability of $6.7 million.

Upon further analyses of the Tax Act and notices and regulations issued and proposed by the U.S. Department of the Treasury and the Internal Revenue Service, as well as certain refinements to our E&P calculations related to our subsidiaries, the Company finalized its calculations of the transition tax liability during 2018. We increased our 2017 provisional amount by $1.9 million, which is included as a component of income tax expense from continuing operations. We have elected to pay our transition tax over eight-year period provided in the Tax Act. As of December 31, 2018, the remaining balance of our transition tax obligation will be paid over the permitted eight year period.

Global intangible low-taxed income (GILTI)

The Tax Act subjects a U.S. shareholder to tax on GILTI earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. Because we were evaluating the provision of GILTI as of December 31, 2017, we recorded no GILTI-related deferred amounts in 2017. After further consideration in the current year, we have elected to account for GILTI as a period expense in the year the tax is incurred; therefore, no deferred taxes are recorded related to GILTI.

Deferred tax liabilities for withholding tax

The excess of financial reporting basis over tax basis of the Company's foreign subsidiaries is considered permanently reinvested with the exception of certain earnings of the Canadian subsidiary. The Company originally recorded a provisional amount of deferred tax liability for withholding and state income taxes associated with the ultimate repatriation from Canada to the U.S. of these earnings of $3.2 million at December 31, 2017. Upon further analysis of its calculations of the Canadian withholding tax, the Company decreased its provisional amount by $2.5 million, which is included as a component of income tax expense from continuing operations.

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The provision for income taxes differs from the amount computed by applying the statutory federal rate to pretax income as follows (in percentages):

	Year Ended December 31,		
	2018	2017	2016
Statutory tax rate	21.0 %	35.0 %	35.0 %
State taxes, net of federal benefit	3.0 %	(1.4)%	1.5 %
Permanent items	2.6 %	0.5 %	9.5 %
Effect of foreign operations	3.4 %	(5.7)%	(9.0)%
Research and incentive tax credit generated	(8.7)%	(4.6)%	(14.3)%
Valuation allowance	0.4 %	(37.6)%	5.5 %
Income tax reserves	24.7 %	0.5 %	1.3 %
Remeasurement U.S. deferreds	(0.3)%	7.3 %	0.0 %
Transition tax	(16.6)%	18.1 %	0.0 %
Foreign earnings withholding tax	(7.9)%	8.6 %	0.0 %
Global intangible low-taxed income	5.7 %	0.0 %	0.0 %
Other measurement period Tax Act adjustments	2.6 %	0.0 %	0.0 %
Canadian income tax audit	4.8 %	0.0 %	0.0 %
Other	(0.1)%	0.1 %	0.1 %
	34.6 %	20.8 %	29.6 %

The Company accounts for income taxes using the asset and liability method in accordance with ASC 740 “Income Taxes” (ASC 740). Under this method, deferred income taxes are recognized for the future tax consequences of differences between the tax and financial accounting bases of assets and liabilities at the end of each reporting period. Deferred income taxes are based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Significant components of the Company’s deferred tax assets and liabilities as of December 31 are as follows (in thousands):

	2018	2017
Deferred tax assets:		
Accrued liabilities and other	$5,646	$6,444
Net operating loss and credit carryforwards	54,167	67,299
Deferred revenue	—	1,541
Depreciation and amortization	—	4,071
Stock compensation and other	6,525	5,429
Gross deferred tax assets	66,338	84,784
Valuation allowance	(21,354)	(21,943)
Total deferred tax assets	$44,984	$62,841
Deferred tax liabilities:		
Accrued liabilities and other	$(2,204)	$(4,207)
Deferred revenue	(358)	—
Depreciation and amortization	(20,952)	(20,155)
Acquired intangibles	—	(927)
Total deferred tax liabilities	(23,514)	(25,289)
Net deferred tax assets	$21,470	$37,552

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The Company has established a valuation allowance against a portion of its remaining deferred tax assets because it is more likely than not that certain deferred tax assets will not be realized. In determining whether deferred tax assets are realizable, the Company considered numerous factors including historical profitability, the amount of future taxable income and the existence of taxable temporary differences that can be used to realize deferred tax assets. The valuation allowance decreased approximately $589,000 in 2018 from 2017 primarily due to releasing valuation allowance of $1.1 million against net deferred tax assets of certain state net operating loss and research carryforwards, and recording increased valuation allowance on the net deferred tax assets for stock compensation of $472,000. Net deferred tax assets of certain state net operating losses offset by valuation allowance expired and the Company released these valuation allowances. We anticipate portions of net deferred tax assets will not be realized under the provisions of Section 162(m) of the Tax Act which limit the deductibility of executive compensation.

At December 31, 2018, the Company had gross federal, state and foreign net operating loss carryforwards of approximately $60.8 million, $349.0 million, and $8.1 million, respectively. These losses expire beginning in 2019. Federal and state net operating losses of approximately $60.8 million and $349.0 million, respectively, were acquired as part of the acquisitions of U.S. companies. These acquired net operating losses are subject to annual limitations due to the “change of ownership” provisions of Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The Company has federal, state and foreign credit carryforwards of approximately $7.1 million, $3.6 million, and $15.1 million, respectively. These credits begin to expire in 2019, except for approximately $1.6 million which have an indefinite carryforward period. Certain of these credits are subject to annual limitations under the change in ownership provisions. Alternative minimum tax credits of $462,000 which are potentially subject to refund under the Tax Act have been reflected as deferred tax assets. In addition, the Company has state research credits of approximately $1.1 million which have an indefinite carryforward period.

The excess of financial reporting basis over tax basis of the Company’s foreign subsidiaries is considered permanently reinvested with the exception of certain earnings of the Canadian subsidiary. The cumulative amount of excess financial reporting basis of the Company’s non-U.S. subsidiaries was approximately $3.8 million at December 31, 2018, $7.4 million at December 31, 2017 and $26.6 million at December 31, 2016. Since the Company does not intend to permanently reinvest portions of its previously taxed Canadian earnings, it has recorded a deferred tax liability of $284,000 related to withholding and state income taxes associated with the ultimate repatriation from Canada to the U.S. of these previously taxed earnings. Beginning January 1, 2018, the Tax Act implemented a territorial tax system in the U.S. such that the income earned by the Company’s non-U.S. subsidiaries will be subject to a 100% dividend received deduction. As such, only potential withholding and state income taxes on the non-permanently reinvested earnings have a deferred tax liability recorded. We have not recognized a deferred tax liability related to withholding taxes on the excess financial reporting basis of our other foreign subsidiaries because the Company currently intends to reinvest earnings of these subsidiaries in operations outside the U.S. Determination of the amount of the unrecognized deferred tax liability on these unremitted earnings is not practicable.

As of December 31, 2018 and December 31, 2017, the Company had recorded gross unrecognized tax benefits of approximately $9.7 million and $2.8 million, respectively. All of the unrecognized tax benefits as of December 31, 2018, if recognized, would impact the effective tax rate. The Company recognizes interest expense and penalties associated with uncertain tax positions as a component of income tax expense. During the years ended December 31, 2018 and 2017, the Company recognized approximately $104,000 and $35,400 in tax related interest and penalties, respectively. Reserves for interest and penalties as of December 31, 2018 and 2017 are not significant as the Company has net operating loss carryovers.

A reconciliation of the beginning and ending balance of unrecognized tax benefits is as follows (in thousands):

	2018	2017
Balance at beginning of year	$2,777	$2,677
Additions based on tax positions related to the current year	749	355

Additions for tax positions of prior years	6,605	—
Reductions for tax positions of prior years	(410)	(103)
Lapse of statute of limitations	—	(152)
Balance at end of year	$9,721	$2,777

As of December 31, 2018, unrecognized tax benefits related to the U.S. transition tax on earnings of certain foreign subsidiaries and U.S. tax on global intangible low tax income of $6.2 million and $453,000, respectively, were recorded. The Company has submitted a ruling for certain aspects of the E&P calculation of its Canadian subsidiary, and if the request is granted, it is reasonably possible that the unrecognized tax benefits will decrease by approximately $6.6 million in the next 12 months.

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The Company files U.S., state, and foreign income tax returns in jurisdictions with varying statutes of limitations. In the United States and Canada, the statute of limitations with respect to the federal income tax returns for tax years after 2012 are open to audit; however, since the Company has net operating losses, the taxing authority has the ability to review tax returns prior to the 2012 tax year and make adjustments to these net operating loss carryforwards. In June and September 2018, the Company recorded an income tax expense totaling $1.4 million based primarily on the results of a Canadian income tax audit. The expense recorded is the net result of reductions to the scientific research and experimental development expenditure pool and investment tax credit carryforward balances and an increase to non-capital carryforward losses. We are not under audit in any major taxing jurisdictions at this time.

NOTE 12 — EARNINGS PER SHARE

A reconciliation of the denominators used in computing per share net income (EPS) is as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2018	2017	2016
Basic:			
Net income	$18,508	$29,423	$13,814
Less: allocation to participating securities	(312)	(529)	—
Net income attributable to common stockholders	$18,196	$28,894	$13,814
Weighted average common stock outstanding	43,727	43,173	42,584
Net income per share attributable to common stockholders	$0.42	$0.67	$0.32
Diluted:			
Net income	$18,508	$29,423	$13,814
Less: allocation to participating securities	(311)	(529)	—
Net income attributable to common stockholders	$18,197	$28,894	$13,814
Weighted average common stock outstanding	43,727	43,173	42,584
Effect of dilutive securities: stock options and awards	564	127	429
Weighted-average shares used in computing net income per share	44,291	43,300	43,013
Net income per share attributable to common stockholders	$0.41	$0.67	$0.32

Basic net income per share is computed by dividing the net income for the period by the weighted average number of common shares outstanding during the period. Diluted net income per share is computed by dividing the net income for the period by the weighted average number of common and common equivalent shares outstanding during the period. Restricted stock awards (RSAs) and stock options to acquire 619,113, 2,182,404, and 2,017,106 shares for the years ended December 31, 2018, 2017 and 2016, respectively, were excluded from the computations of diluted earnings per share because the effect of including the RSAs and stock options would have been anti-dilutive.

We apply the two-class method of computing earnings per share, which requires the calculation of separate earnings per share amounts for our non-vested, time-based restricted stock awards with non-forfeitable dividends and for our common stock. Our non-vested, time-based restricted stock awards with non-forfeitable dividends are considered securities which participate in undistributed earnings with common stock. Under the two-class computation method, net losses are not allocated to participating securities unless the holder of the security has a contractual obligation to share in the losses. Our non-vested, time-based restricted stock awards with non-forfeitable dividends do not have such an obligation so they are not allocated losses.

NOTE 13 — STOCKHOLDERS' EQUITY, EMPLOYEE BENEFIT PLANS AND STOCK-BASED COMPENSATION

Preferred Stock

The Company’s Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences and the number of shares constituting any series or the designation of such series, without further vote or action by the Company’s stockholders. At December 31, 2018 and 2017, there was no preferred stock issued and outstanding.

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Dividends

In February 2017, the Board of Directors initiated a cash dividend program under which the Company began paying a regular quarterly cash dividend. On February 21, 2017, May 24, 2017, September 12, 2017 and December 7, 2017 the Board of Directors declared cash dividends on the Company's common stock of $0.06 per share, respectively. The dividend declared in February was payable to stockholders of record as of March 24, 2017 and was paid on April 14, 2017. The dividend declared in May was payable to stockholders of record as of June 23, 2017 and was paid on July 14, 2017. The dividend declared in September was payable to stockholders of record as of September 22, 2017 and was paid on October 13, 2017. The dividend declared in December was payable to stockholders of record as of December 22, 2017 and was paid on January 12, 2018.

On January 24, 2018, May 18, 2018, September 11, 2018 and December 11, 2018 the Board of Directors declared cash dividends on the Company's common stock of $0.06 per share, respectively. The dividend declared in January was payable to stockholders of record as of March 23, 2018 and was paid on April 13, 2018. The dividend declared in May was payable to stockholders of record as of June 22, 2018 and was paid on July 13, 2018. The dividend declared in September was payable to stockholders of record as of September 21, 2018 and was paid on October 12, 2018. The dividend declared in December was payable to stockholders of record as of December 22, 2018 and was paid on January 10, 2019. The Company's current intent is to pay a continuing dividend on a quarterly basis. However, future declaration of dividends is subject to the final determination of the Company's Board of Directors.

Stock-Based Compensation

At December 31, 2018, the Company has one stock-based employee compensation plan pursuant to which grants may be made: the Luminex Corporation 2018 Equity Incentive Plan (Equity Incentive Plan) which was approved at the Company's Annual Meeting on May 17, 2018. No further grants shall be made pursuant to the 2000 Long-Term Incentive Plan (2000 Plan), the 2001 Broad-Based Stock Option Plan (2001 Plan) or the 2006 Equity Incentive Plan (2006 Plan). In addition, at December 31, 2018, the Company has one plan pursuant to which discount purchases may be made by the participants in such plan: the Luminex Corporation Employee Stock Purchase Plan (ESPP), which was approved at the Company's Annual Meeting on May 17, 2012 and amended at the Company's Annual Meeting on May 18, 2017.

Equity Incentive Plans

Under the Company's Equity Incentive Plan, the 2006 Plan, certain employees, consultants and non-employee directors have been granted RSAs, restricted share units (RSUs) and options to purchase shares of common stock. The options, RSAs, and RSUs generally vest in installments over a three to five year period, and the options expire either seven or ten years after the date of grant. Under the Equity Incentive Plan, certain employees of, directors of, and consultants to the Company are eligible to be granted RSAs, RSUs, and options to purchase common stock.

The ESPP provides for the granting of rights to certain employees of the Company to defer an elected percentage, up to 15%, of their base salary through the purchase of the Company's common stock, discounted by 15%. As of December 31, 2018, there were approximately 4.8 million shares authorized for future issuance under the Company's Equity Incentive Plan and approximately 324,000 shares eligible for purchase pursuant to the terms and conditions of the ESPP as more fully described below.

The Equity Incentive Plan, the 2006 Plan and the ESPP are administered by the Compensation Committee of the Board of Directors. The Compensation Committee has the authority to determine the terms and conditions under

which awards will be granted from the Equity Incentive Plan, including the number of shares, vesting schedule and term, as applicable. Any option exercise prices, as set forth in the Equity Incentive Plan, will be equal to the fair market value on the date of grant. Under certain circumstances, the Company may repurchase previously granted RSAs and RSUs.

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On each of March 10, 2017 and February 21, 2018, the Compensation Committee approved an award of stock options (the Performance Options) to the Company's named executive officers and certain other executives that vest over four years based on achievement of certain operating profit and revenue targets in 2017 and 2018, respectively. The Performance Options have an exercise price equal to the closing market price for the Company's common stock on the Nasdaq Global Select Market on the date of grant (March 10, 2017 and March 12, 2018, respectively) and expire seven years from the date of grant. The Performance Options were measured over a performance period ending on December 31, 2017 and December 31, 2018, respectively. Following the end of the applicable fiscal year, the Committee determined the number of Performance Options which were eligible to vest based upon the level of achievement of an established Company performance goal (the Company Financial Goal). If the Company failed to meet the threshold performance for the performance period, no Performance Options would be eligible to vest. Minimum vesting for minimum threshold performance started at 30% of the target value for the Company Financial Goal. If the Company's performance exceeded the target performance, the recipient may have received additional Performance Options above the target number, subject to a maximum of 200% of the target award. The Company's financial performance resulted in delivery of 148% and 115% of the number of target Performance Options granted for 2017 and 2018, respectively. The Performance Options that are eligible to vest after the determination date will vest 25% on each of the first four anniversaries of the grant date. In the event of a change of control of the Company before the end of the performance period, the Performance Options will automatically vest based on the greater of actual achievement of the pro-rated Company Financial Goal as of the date of the change of control or 100% of target performance, as determined by the Committee in its sole discretion. The Performance Options are exercisable into shares of the Company's common stock.

Accounting for Stock Compensation

Stock-based compensation costs are generally based on the fair value calculated from the Black-Scholes option-pricing model on the date of grant for stock options, performance options and market value on the date of grant for RSAs. The fair values of stock and stock options are amortized as compensation expense on a straight-line basis over the vesting period of the grants.

In accordance with ASC 718, the Company evaluates the assumptions used in the Black-Scholes model at each grant date using a consistent methodology for computing expected volatility, expected term and risk-free rate of return. Calculation of expected volatility is based on historical volatility. The expected life is calculated using the contractual term of the options as well as an analysis of the Company's historical exercises of stock options and performance options. The estimate of the risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. The dividend yield is based on our history and expectation of dividend payouts at the time of grant. The assumptions used are summarized in the following table:

	2018	2017	2016
Dividend yield	1.2 %	1.3 %	— %
Expected volatility	0.4	0.5	0.5
Risk-free rate of return	2.7 %	2.0 %	1.4 %
Expected life of a 10 year contractual term option	7 years	7 years	7 years
Expected life of a 7 year contractual term option	4.88 years	4.87 years	4.87 years
Weighted average fair value at grant date	$8.23	$6.66	$7.86

As part of the requirements of ASC 718, the Company is required to estimate potential forfeitures of stock grants and adjust compensation cost recorded accordingly. The estimate of forfeitures is based on historical forfeiture performance and will be adjusted over the requisite service period to the extent that actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative

catch-up adjustment in the period of evaluation and will also impact the amount of stock compensation expense to be recognized in future periods.

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The Company's stock option activity for the years ended December 31, 2016, 2017 and 2018 is as follows:

Stock Options	Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2015	1,692	$ 17.47		
Granted	886	19.21		
Exercised	(178)	18.55		
Canceled or expired	(220)	17.83		
Outstanding at December 31, 2016	2,180	$ 18.06		
Granted	1,406	18.08		
Exercised	(172)	16.50		
Canceled or expired	(328)	18.39		
Outstanding at December 31, 2017	3,086	$ 18.10		
Granted	771	22.15		
Exercised	(158)	17.84		
Canceled or expired	(376)	18.56		
Outstanding at December 31, 2018	3,323	$ 19.05	4.61	$ 13,608
Vested at December 31, 2018 and expected to vest	3,275	$ 19.03	4.59	$ 13,472
Exercisable at December 31, 2018	1,337	$ 18.16	3.69	$ 6,615

During the years ended December 31, 2018, 2017 and 2016, the total exercise intrinsic value of stock options exercised was $1.3 million, $0.7 million and $0.6 million, respectively, and the total fair value of stock options that vested was $12.7 million, $12.7 million and $1.6 million, respectively. Exercise intrinsic value represents the difference between the market value of the Company's common stock at the time of exercise and the price paid by the employee to exercise the options. The Company had $8.7 million of total unrecognized compensation costs related to stock options at December 31, 2018 that are expected to be recognized over a weighted-average period of 2.23 years.

The Company's restricted share activity for the years ended December 31, 2016, 2017 and 2018 is as follows:

Restricted Stock Awards	Shares (in thousands)	Weighted Average Grant Price
Non-vested at December 31, 2015	836	$ 18.66
Granted	301	19.76
Vested	(231)	19.75
Cancelled or expired	(96)	18.78
Non-vested at December 31, 2016	810	$ 18.74
Granted	370	18.22
Vested	(354)	18.74
Cancelled or expired	(112)	18.84
Non-vested at December 31, 2017	715	$ 18.46
Granted	387	22.21
Vested	(313)	18.70
Cancelled or expired	(66)	19.58
Non-vested at December 31, 2018	724	$ 20.27

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Restricted Stock Units	Shares (in thousands)	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Non-vested at December 31, 2015	501		
Granted	99		
Vested	(83)		
Cancelled or expired	(61)		
Non-vested at December 31, 2016	457		
Granted	104		
Vested	(122)		
Cancelled or expired	(16)		
Non-vested at December 31, 2017	423		
Granted	95		
Vested	(47)		
Cancelled or expired	(3)		
Non-vested at December 31, 2018	468	1.10	$ 10,834
Vested at December 31, 2018 and expected to vest	417	1.06	$ 10,678
Exercisable at December 31, 2018	273	0.00	$ 7,373

As of December 31, 2018, there was $14.5 million of unrecognized compensation cost related to RSAs and RSUs. That cost is expected to be recognized over a weighted average-period of 2.24 years. The total fair value of restricted shares vested during the year ended December 31, 2018, 2017 and 2016 was $6.7 million, $8.8 million and $7.0 million, respectively.

RSAs and RSUs may be granted at the discretion of the Compensation Committee of the Board of Directors under the Equity Incentive Plan and the 2006 Plan in connection with the hiring or retention of key employees and are subject to certain conditions. Restrictions expire at certain dates after the grant date in accordance with specific provisions in the applicable agreement. During the year ended December 31, 2018, the Company awarded 387,436 shares of RSAs, which had a fair value at the date of grant ranging from $20.33–$29.33. During the year ended December 31, 2017, the Company awarded 369,715 shares of RSAs, which had a fair value at the date of grant ranging from $18.04–$20.80. During the year ended December 31, 2016, the Company awarded 301,419 shares of RSAs, which had a fair value at the date of grant ranging from $19.48–$22.59. During the year ended December 31, 2018, the Company awarded 95,127 shares of RSUs and dividend equivalents, which had a fair value at the date of grant ranging from $21.98–$26.39. During the year ended December 31, 2017, the Company awarded 104,237 shares of RSUs and dividend equivalents, which had a fair value at the date of grant ranging from $18.04–$20.80. During the year ended December 31, 2016, the Company awarded 99,144 shares of RSUs, which had a fair value at the date of grant ranging from $19.48–$20.62. Compensation under these RSAs and RSUs was charged to expense over the restriction period and amounted to $6.2 million, $7.2 million, and $7.9 million in 2018, 2017 and 2016, respectively. There were no significant stock compensation costs capitalized into assets as of December 31, 2018, 2017 or 2016.

The Company received $2.8 million, $2.8 million and $3.3 million for the exercise of stock options during the years ended December 31, 2018, 2017 and 2016, respectively. Cash was not used to settle any equity instruments previously granted. The Company issued shares pursuant to grants relating to each of the Equity Incentive Plan, the 2006 Plan and 2000 Plan from reserves upon the exercise of stock options and vesting of RSAs.

The following are the stock-based compensation costs recognized in the Company’s consolidated statements of comprehensive income (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cost of revenue	$1,715	$1,561	$1,247
Research and development	1,409	2,039	2,658
Selling, general and administrative	9,102	8,878	7,916
Stock-based compensation costs reflected in net income	$12,226	$12,478	$11,821

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Employee Stock Purchase Plan

In May 2012, the Company's stockholders approved the ESPP, which provides for the purchase of up to 500,000 shares of the Company's common stock by eligible employees. In May 2017, the Company's stockholders approved an amendment to the ESPP Plan, which increased the shares available under the ESPP by 341,744 shares. The ESPP period is semi-annual and allows participants to purchase the Company's common stock at 85% of the lesser of (i) the closing market value per share of the common stock on the first trading date of the option period or (ii) the closing market value per share of the common stock on the last trading date of the option period. As of December 31, 2018, 2017 and 2016, 518,111 shares, 434,400 shares and 341,844 shares, respectively had been issued out of the ESPP. The related stock-based compensation expense was $0.6 million, $0.5 million and $0.4 million for 2018, 2017 and 2016, respectively.

The Company uses the Black-Scholes model to estimate the fair value of shares to be issued under the ESPP as of the grant date using the following weighted average assumptions:

	2018	2017	2016
Assumptions:			
Risk-free interest rates	2.1 %	1.07 %	0.04% to 0.05%
Expected life	0.5 years	0.5 years	0.4 to 0.5 years
Expected volatility	.44	.45	.47
Dividend yield	1.2 %	1.3 %	— %

Reserved Shares of Common Stock

At December 31, 2018 and 2017, the Company had reserved 8,925,957 and 6,270,286 shares of common stock, respectively, for the issuance of common stock upon the exercise of options, issuance of RSAs, RSUs, purchase of common stock pursuant to the ESPP or other awards issued pursuant to the Company's equity plans and arrangements. The following table summarizes the reserved shares by plan as of December 31, 2018:

	Options and RSUs Outstanding	Shares Available for Future Issuance	Total Shares Reserved
Equity Incentive Plan	3,791,819	4,810,505	8,602,324
ESPP	—	323,633	323,633
	3,791,819	5,134,138	8,925,957

Employee Savings Plans and Other Benefit Plans

Effective January 1, 2001, the Company began sponsoring a retirement plan authorized by section 401(k) of the Internal Revenue Code for the Company's employees in the United States. In accordance with the 401(k) plan, all employees are eligible to participate in the plan on the first day of the month following the commencement of full time employment. For 2018, 2017 and 2016, each employee could contribute a percentage of compensation up to a maximum of $18,500 per year, with the Company matching 50% of each employee's contributions. Effective January 1, 2010, the Company began contributing to a deferred profit sharing plan for its Canadian employees. All Canadian employees are eligible to participate in the plan. The Company's contributions to these plans for 2018, 2017 and 2016 were $4.0 million, $3.8 million and $3.2 million, respectively.

Several of the Company's Netherlands employees are covered by a defined benefit plan. The cost and total liability to the Company is not material. Effective January 1, 2011, all of the Company's new hires in the Netherlands are eligible to participate in a defined contribution plan.

NOTE 14 — COMMITMENTS AND CONTINGENCIES

Lease Arrangements

The Company has operating leases related primarily to its office and manufacturing facilities with original lease periods of up to ten years. Rental and lease expense for these operating leases for the years 2018, 2017 and 2016 totaled approximately $7.0 million, $6.6 million and $5.8 million, respectively.

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Minimum annual lease commitments as of December 31, 2018 under non-cancellable leases for each of the next five years and in the aggregate were as follows (in thousands):

2019	$5,747
2020	5,546
2021	5,457
2022	4,080
2023	3,540
Thereafter	2,813
Total	$27,183

These non-cancellable lease commitments related to facilities include certain rent escalation provisions which have been included in the minimum annual rental commitments shown above. These amounts are recorded to expense on a straight-line basis over the life of the lease. In addition, some of the Company's leases contain options to renew the lease for five to ten years at the then prevailing market rental rate, right of first refusal to lease additional space that becomes available, or leasehold improvement incentives.

Non-Cancellable Purchase Commitments

As of December 31, 2018 the Company had approximately $39.6 million in purchase commitments primarily with several of its inventory suppliers as well as other operating commitments. Certain of our supply agreements require purchase and delivery of minimum amounts of components through 2018, and purchases under these arrangements were $2.2 million, $1.8 million and $2.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Employment Contracts

The Company has entered into employment contracts with certain of its key executives. Generally, certain amounts may become payable in the event the Company terminates the executives' employment without cause or the executive resigns for good reason.

Legal Proceedings

In the normal course of business, the Company is subject to claims, lawsuits and legal proceedings. When and if it appears probable in management's judgment, and based upon consultation with outside counsel, that we will incur monetary damages or other costs in connection with any claims or proceedings, and such costs can be reasonably estimated, we record the estimated liability in the financial statements. If only a range of estimated losses can be estimated, we record an amount within the range that, in management's judgment, reflects the most likely outcome; if none of the estimates within that range is a better estimate than any other amount, we record the liability at the low end of the range of estimates. Any such accrual would be charged to expense in the appropriate period. We disclose significant contingencies when the loss is not probable and/or the amount of the loss is not estimable, when we believe there is at least a reasonable possibility that a loss has been incurred. We recognize costs associated with legal proceedings in the period in which the services were provided.

NOTE 15 — GUARANTEES

The terms and conditions of the Company's development and supply and license agreements with its strategic partners generally provide for a limited indemnification of such partners, arising from the sale of Luminex systems and consumables, against losses, expenses and liabilities resulting from third-party claims based on an alleged infringement on an intellectual property right of such third party. The terms of such indemnification provisions generally limit the scope of and remedies for such indemnification obligations to a multiple of amounts paid by such

strategic partner to Luminex during the previous annual period(s). To date, the Company has not had to reimburse any of its strategic partners for any losses arising from such indemnification obligations.

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NOTE 16 — GEOGRAPHIC INFORMATION

The table below provides information regarding product revenues and property and equipment, net from the Company's sales to customers within the United States and in foreign countries for the years ended December 31 (in thousands):

	Sales to Customers			Property and Equipment, net		
	2018	2017	2016	2018	2017	2016
Domestic	$261,726	$256,834	$222,706	$63,382	$54,623	$53,283
Foreign:						
Europe	21,672	20,378	19,211	394	809	1,079
Asia	21,603	20,134	20,733	519	741	730
Canada	4,775	4,386	3,738	1,993	2,077	2,274
Other	6,042	4,839	4,251	—	8	9
	$315,818	$306,571	$270,639	$66,288	$58,258	$57,375

The Company's aggregate foreign currency transaction losses of $487,000, $134,000 and $121,000 were included in determining the consolidated results for the years ended December 31, 2018, 2017 and 2016, respectively.

NOTE 17 — RECENT ACCOUNTING PRONOUNCEMENTS

Recently adopted accounting guidance

In May 2014, the Financial Accounting Standards Board (FASB) issued a new standard on revenue recognition, Accounting Standards Codification 606 (the Standard) which outlines a single comprehensive model to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The core principle of the revenue model is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company adopted the Standard effective January 1, 2018, using the modified retrospective approach. Under this method, the Company recorded a cumulative adjustment increasing retained earnings of $10.6 million before related tax impacts or $8.1 million net of related tax impacts. See Note 18, "Revenue Recognition" for additional discussion related to the Company's adoption of the Standard. Under the Standard, estimated royalty revenue will be recorded each quarter on an accrual basis to more closely coincide with the timing of the end user sale by the strategic partner; with reconciliation made upon submission of the royalty report by the partner indicating actual royalties owed in the following quarter. In addition, the Company began recording the portion of reagent rental revenue associated with the recovery of the cost of providing the system and other hardware in reagent rental agreements as system revenue rather than assay revenue effective January 1, 2018. This change has not and is not expected to have any impact on top line revenue and the Company does not anticipate any material effects to its revenue categorization.

In January 2016, the FASB issued guidance that amends various aspects of the recognition, measurement, presentation, and disclosure for financial instruments. This guidance was effective for annual reporting periods, and interim periods within those years beginning after December 15, 2017. The Company adopted this standard during the quarter ended March 31, 2018. The adoption of this new standard resulted in a change to the Company's accounting policy; however, adoption did not have a material impact on its consolidated financial position or results of operations.

In August 2016, the FASB issued specific guidance on eight cash flow classification issues that are not currently addressed by current U.S. GAAP and thereby reduce the current diversity in practice. This guidance is effective for annual periods beginning after December 15, 2017. The Company adopted this standard during the quarter ended

March 31, 2018, and its adoption did not have a material impact on the Company's consolidated financial statements.

In October 2016, the FASB issued guidance on income taxes which requires companies to recognize the income tax effects of intercompany sales and transfers of assets, other than inventory, in the statement of comprehensive income as income tax expense (or benefit) in the period in which the transfers occur. The new standard became effective for the Company on January 1, 2018. The Company has adopted this new standard using the modified retrospective method through a cumulative-effect adjustment, based on currently enacted tax rates, directly to retained earnings as of the beginning of that date. The adoption of this new standard resulted in a change to the Company's accounting policy; however, adoption did not have a material impact on the Company's consolidated financial position or results of operations.

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On January 10, 2018, the FASB issued guidance on the accounting for tax on the GILTI provisions of the Tax Act. The GILTI provisions impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. Effective January 1, 2018, the Company recognizes the tax on GILTI as a period expense in the period the tax is incurred. Under this policy, the Company has not provided deferred taxes related to temporary differences that upon their reversal will affect the amount of income subject to GILTI in the period.

In January 2018, the FASB issued guidance related to reporting comprehensive income, which gives entities the option to reclassify to retained earnings the tax effects resulting from the Tax Act related to items in Additional Other Comprehensive Income (AOCI) that the FASB refers to as having been “stranded” in AOCI. The guidance is effective for annual and interim periods beginning after December 15, 2018, and is applicable to the Company in fiscal year 2019; however, early adoption is permitted. The Company does not have any tax effects resulting from the Tax Act that are stranded in AOCI and therefore this guidance has no impact on its consolidated financial statements. The Company early adopted this guidance and established the accounting policy for reclassifying to retained earnings any tax effects resulting from the Tax Act that are stranded in AOCI.

In June 2018, the FASB issued guidance which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. For public business entities, the guidance is effective for annual periods beginning after December 15, 2018, and interim periods within those annual periods; however, early adoption is permitted. Although nonemployee directors do not satisfy the definition of employee, under FASB guidance, the Company’s nonemployee directors acting in their role as members of a board of directors are treated as employees as those directors were elected by the Company’s shareholders. Therefore, awards granted to these nonemployee directors for their services as directors already were accounted for as employee awards. The Company early adopted this guidance, which did not have a material impact on its consolidated financial statements.

In August 2018, the FASB issued guidance that eliminates, adds and modifies certain disclosure requirements for fair value measurements. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but public companies will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The guidance is effective for annual and interim periods beginning after December 15, 2019, but entities are permitted to early adopt either the entire standard or only the provisions that eliminate or modify the requirements. The Company early adopted this guidance, which did not have a material impact on its consolidated financial statements.

In September 2018, the Securities and Exchange Commission (SEC) issued interpretive guidance relating to previously adopted amendments to certain disclosure requirements, including those related to interim disclosures about changes in stockholders’ equity and non-controlling interests. The guidance extends the annual requirement to disclose: (1) changes in stockholders’ equity and (2) the amount of dividends per share for each class of shares (as opposed to common stock only, as previously required) to interim periods. The amendments are effective for all filings made on or after November 5, 2018. However, the interpretive guidelines indicate that the SEC would not object if a filer’s first presentation of the change in stockholders’ equity is included in its 10-Q for the quarter that begins after the effective date of the amendments. The Company has adopted this guidance during the quarter ended September 30, 2018 by including prior year, comparative periods in its Consolidated Statement of Changes in Stockholders’ Equity.

In January 2017, the FASB issued guidance on intangibles, including goodwill, which simplifies how companies calculate goodwill impairments by eliminating Step 2 of the impairment test. The guidance requires companies to compare the fair value of a reporting unit to its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value. The guidance is effective for annual periods beginning after December 15, 2019, and is applicable to the Company in fiscal year 2020; however, early adoption is

permitted. The Company early adopted this guidance in the fourth quarter of 2018, which did not have a material impact on its consolidated financial statements.

Recent accounting guidance not yet adopted

In June 2016, the FASB issued guidance on financial instruments and related credit losses. The guidance requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis. The statement of comprehensive income reflects the measurement of credit losses for newly recognized financial assets, as well as the expected credit losses during the period. The measurement of expected credit losses is based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. The updated guidance is effective for annual periods beginning after December 15, 2019, and is applicable to the Company in fiscal 2020. Early adoption is permitted. The Company does not anticipate that this guidance will have a material impact on its consolidated financial statements.

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In February 2016, the FASB issued guidance requiring lessees to recognize a right-of-use asset and a lease liability on the balance sheet for all leases, with the exception of short-term leases. The effective date of the new guidance is for the Company's first quarter of fiscal year 2019; however, early adoption is permitted. The FASB has approved an optional, alternative method to adopt the lease standard by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company adopted the new standard effective January 1, 2019, using the alternative method. With the implementation of the standard, the Company will recognize right-to-use assets and lease liabilities for operating leases of approximately $25 million. The Company will not have a cumulative adjustment impacting retained earnings. Adoption of the lease standard will not have a material impact on the Company's consolidated statement of comprehensive income nor on its consolidated cash flows statements.

NOTE 18 — REVENUE RECOGNITION

On January 1, 2018, the Company adopted the Standard on revenue recognition, using the modified retrospective transition method consistent with the guidance issued by the FASB in May 2014. Under this method, the Company applied the guidance retrospectively, only to those contracts which were not completed as of the date of initial application, and recognized the cumulative effect of initially applying the Standard as an adjustment to the opening balance of retained earnings as of January 1, 2018. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

The Standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under the Standard, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of the Standard, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of the Standard, the Company assesses the goods or services promised within each contract, identifies the performance obligations and assesses whether each promised good or service is distinct. The Company allocates the total transaction price to each performance obligation in an amount based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation and recognizes as revenue when such performance obligation is satisfied.

Contract assets are included within Accounts receivables, net and contract liabilities are included in Deferred revenue on the Company's Balance Sheet. The following table presents the opening and closing balances of the Company's contract assets and liabilities for the twelve months ended December 31, 2018 (in thousands):

	Balance at Beginning of Period	Balance at End of Period
Contract assets:		
Unbilled receivables - Royalties	$ 10,643	$10,805
Contract liabilities - short-term:		
Deferred revenue - Service [1]	$ 4,438	$9,476
Deferred revenue - Licenses	246	227
Deferred revenue - Other	37	396

Total Contract liabilities - short-term	$ 4,721	$10,099
Contract liabilities - long-term:		
Deferred revenue - Service	$ 315	$207
Deferred revenue - Licenses	1,099	872
Deferred revenue - Other	83	—
Total Contract liabilities - long-term	$ 1,497	$1,079

(1) Note - 2018 contract liabilities includes $4.4 million of deferred service revenue which was acquired through the acquisition of EMD Millipore Corporation’s flow cytometry portfolio on December 31, 2018.

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During the twelve months ended December 31, 2018, the Company recognized the following revenues as a result of changes in the contract asset and contract liability balances in the period (in thousands):

	Year Ended December 31, 2018
Revenue recognized in the period:	
Amounts included as contract liabilities at the beginning of the period	$ 4,751
Performance obligations satisfied in previous periods	-

In accordance with the Standard, the disclosure of the impact of adoption on our consolidated statement of comprehensive income and balance sheet was as follows (in thousands):

	Three Months Ended December 31, 2018			Year Ended December 31, 2018		
Statement of Comprehensive Income	As Reported in this Annual Report	Amounts Before Adoption of the Standard	Net Effect of Adoption of the Standard	As Reported in this Annual Report	Amounts Before Adoption of the Standard	Net Effect of Adoption of the Standard
System sales	$10,209	$ 9,378	$ 831	$39,986	$37,450	$ 2,536
Consumable sales	15,678	15,678	—	50,144	50,144	—
Royalty revenue	13,507	13,439	68	49,394	49,145	249
Assay revenue	36,952	37,765	(813)	156,714	159,335	(2,621)
Other revenue	4,787	4,787	—	19,580	19,580	—
Revenue	81,133	81,047	86	315,818	315,654	164
Gross profit	48,341	48,255	86	195,491	195,327	164
Income from operations	968	882	86	27,846	27,682	164
Income tax benefit (expense)	(3,263)	(3,242)	(21)	(9,803)	(9,763)	(40)
Net Income	(2,295)	(2,360)	65	18,508	18,384	124

	As of December 31, 2018		
Balance Sheet	As Reported in this Annual Report	Balances Before Adoption of ASC 606	Effect of Adoption of the Standard
ASSETS			
Accounts receivable, net	53,396	42,589	10,807
Deferred income taxes	21,470	24,063	(2,593)
LIABILITIES AND STOCKHOLDERS' EQUITY			
Retained earnings	103,390	95,176	8,214

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NOTE 19 — SELECTED QUARTERLY RESULTS (UNAUDITED)

The following table sets forth certain quarterly financial data for the periods indicated (in thousands, except per share data):

	Quarter Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Revenue	$82,662	$79,578	$ 72,445	$81,133
Gross profit	53,588	49,306	44,256	48,341
Income (loss) from operations	15,266	7,858	3,754	968
Net income (loss)	13,397	5,669	1,737	(2,295)
Basic income (loss) per common share	0.30	0.13	0.04	(0.05)
Diluted income (loss) per common share	0.30	0.13	0.04	(0.05)
Cash dividends per common share	0.06	0.06	0.06	0.06

	Quarter Ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
Revenue	$77,779	$76,457	$ 74,136	$78,199
Gross profit	52,786	50,061	45,819	50,380
Income from operations	14,012	7,482	6,529	9,130
Net income [(1)]	9,231	5,544	17,613	(2,965)
Basic income per common share	0.21	0.13	0.40	(0.07)
Diluted income per common share	0.21	0.13	0.40	(0.07)
Cash dividends per common share	0.06	0.06	0.06	0.06

[(1)] Net income in the third quarter of 2017 included an income tax benefit from the release of a portion of the valuation allowance on deferred tax assets in Canada. See Note 11 – Income Taxes.

See Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations for further discussion.

NOTE 20 — SUBSEQUENT EVENTS

On February 26, 2019, the Company reached an agreement with LabCorp whereby LabCorp has agreed to extend its commitment to the Luminex Cystic Fibrosis product line through December 31, 2021.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

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ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934 (Exchange Act), which are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. We carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on the evaluation and criteria of these disclosure controls and procedures, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective at a reasonable assurance level and designed to ensure that material information relating to the Company and its subsidiaries would be made known to such officers on a timely basis.

Management's Report on Internal Control Over Financial Reporting

On December 31, 2018, the Company completed its acquisition of EMD Millipore Corporation's flow cytometry portfolio (the Acquisition). In conducting management's evaluation for fiscal year 2018, as permitted under SEC rules, our management has currently elected to exclude the Acquisition from its evaluation of the effectiveness of the Company's internal controls over financial reporting as of December 31, 2018.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15 d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the 2013 framework in Internal Control - Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on that evaluation, excluding the Acquisition as noted above, our management concluded that our internal control over financial reporting was effective as of December 31, 2018. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of change in conditions, or that the degree of the compliance with the policies or procedures may deteriorate.

Our independent registered public accounting firm, Ernst & Young LLP, has issued a report on their assessment of the effectiveness of our internal control over financial reporting, which is provided in Item 8 "Financial Statements and Supplementary Data," page 66.

Changes in Internal Control Over Financial Reporting

We are in the process of integrating the Acquisition into our system of internal controls over financial reporting. The acquired flow cytometry portfolio represented approximately constituted 3% and 2% of total and net assets, respectively, as of December 31, 2018.

Other than the forgoing, there have been no changes in our internal control over financial reporting identified in connection with the evaluation required by Exchange Act Rule 13a-15(d) during the fourth quarter of 2018 that have

materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item concerning our directors, audit committee, and audit committee financial experts, code of ethics and compliance with Section 16(a) of the Exchange Act is incorporated by reference to information under the captions “Proposal 1 - Election of Class I Directors”, “Corporate Governance” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our definitive proxy statement for our 2019 Annual Meeting of Stockholders to be held on or about May 16, 2019 (Proxy Statement). It is anticipated that our Proxy Statement will be filed with the Securities and Exchange Commission on or about April 3, 2019.

Pursuant to General Instruction G(3), certain information with respect to our executive officers is set forth under the caption “Executive Officers of the Registrant as of February 25, 2019” in Item 1 of this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

Information required by this Item is incorporated by reference to the section of the Proxy Statement entitled “Executive and Director Compensation.”

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information required by this Item is incorporated by reference to the section of the Proxy Statement entitled “Security Ownership of Certain Beneficial Owners and Management.”

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth, as of December 31, 2018, certain information with respect to shares of our common stock authorized for issuance under our equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Restricted Stock Units	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A))
	(A)	(B)[2]	(C)
Equity compensation plans approved by security holders[1]	3,791,819	$ 19.05	5,134,138
Equity compensation plans not approved by security holders	—	$ —	—
Total	3,791,819		5,134,138

[1] Includes approximately 324,000 shares that are issuable upon vesting of outstanding restricted stock units. The remaining balance consists of outstanding stock option grants.

(2) The weighted average exercise price does not take into account the shares issuable upon vesting of outstanding restricted stock units, which have no exercise price.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by this Item is incorporated by reference to the sections of the Proxy Statement entitled “Certain Relationships and Related Party Transactions” and “Corporate Governance.”

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by this Item is incorporated by reference to the section of the Proxy Statement entitled “Ratification of Appointment of Independent Registered Public Accounting Firm.”

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PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as a part of this Annual Report on Form 10-K:

(1) Financial Statements:

The Financial Statements required by this item are submitted in Part II, Item 8 of this report.

(2) Financial Statement Schedules:

All schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or in the notes thereto.

(3) Exhibits:

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
2.1*	Share and Asset Purchase Agreement made as of October 18, 2018 by and between EMD Millipore Corporation, and IRIS Biotech Corp. (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed on October 18, 2018).
2.2*	Agreement and Plan of Merger, dated as of May 15, 2016, between Luminex Corporation, Commodore Acquisition, Inc., and Nanosphere, Inc. (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed on May 16, 2016).
2.3	First Amendment to the Agreement and Plan of Merger, dated as of May 22, 2016, between Luminex Corporation, Commodore Acquisition, Inc., and Nanosphere, Inc. (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed on May 23, 2016).
2.4	Second Amendment to the Agreement and Plan of Merger, dated as of June 1, 2016, among Luminex Corporation, Commodore Acquisition, Inc., and Nanosphere, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K (File No. 001-33775) filed by Nanosphere, Inc. with the Securities and Exchange Commission on June 2, 2016).
3.1	Restated Certificate of Incorporation of the Company (Previously filed as Exhibit 3.1 to the Company's Registration Statement on Form S-1 (File No. 333-96317), filed February 7, 2000, as amended).
3.2	Amended and Restated Bylaws of the Company (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed March 11, 2015).
10.1#	Form of Indemnification Agreement between the Company and each of the directors and executive officers of the Company (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed September 16, 2008).
10.2	Lease Agreement between Aetna Life Insurance Company, as Landlord, and Luminex Corporation, as Tenant, dated October 19, 2001 (Previously filed as an Exhibit to the Company's Quarterly Report on

	Form 10-Q (File No. 000-30109) for the quarterly period ended September 30, 2001).
10.3	First Amendment to Lease Agreement between Aetna Life Insurance Company, as Landlord, and Luminex Corporation, as Tenant, dated July 25, 2002 (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended June 30, 2002).
10.4	Lease Amendment between McNeil 4 & 5 Investors, LP, as Landlord, and Luminex Corporation, as Tenant, dated January 27, 2003 (Previously filed as an Exhibit to the Company's Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2002).
10.5	Lease Agreement between PS Business Parks, L.P., as Landlord, and Luminex Corporation, as Tenant, dated September 30, 2014 (Previously filed as an Exhibit to the Company’s Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2014).
10.6#	Employment Agreement, effective as of October 1, 2003, by and between Luminex Corporation and Harriss T. Currie (Previously filed as an Exhibit to the Company's Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2003).

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10.7#	Luminex Corporation Amended and Restated 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed May 21, 2009).
10.8#	Form of Non-Qualified Stock Option Agreement for the Amended and Restated 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed May 21, 2009).
10.9#	Form of Restricted Share Award Agreement for Officers & Employees for the Amended and Restated 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed May 21, 2009).
10.10#	Form of Restricted Share Award Agreement for Directors for the Amended and Restated 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed May 21, 2009).
10.11#	Form of Restricted Share Unit Agreement for Officers & Employees for the Amended and Restated 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed May 21, 2009).
10.12#	Form of Restricted Share Unit Agreement for Directors for the Amended and Restated 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed May 21, 2009).
10.13#	Amendment to Luminex Corporation Amended and Restated 2000 Long-Term Incentive Plan dated as of May 24, 2007 (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended June 30, 2007).
10.14#	Luminex Corporation 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Proxy Statement (File No. 000-30109) for its Annual Meeting of Shareholders held on May 25, 2006).
10.15#	Form of Non-Qualified Stock Option Agreement for the 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed May 25, 2006).
10.16#	Form of Restricted Share Award Agreement for Officers & Employees for the 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed May 25, 2006).
10.17#	Form of Restricted Share Award Agreement for Directors for the 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed May 25, 2006).
10.18#	Form of Restricted Share Unit Agreement for the 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2006).
10.19#	Form of Amendments to Equity Award Agreements (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended June 30, 2007).
10.20#	Luminex Corporation Second Amended and Restated 2006 Equity Incentive Plan (Previously filed as Annex A to the Company's Proxy Statement (filed with the Securities and Exchange Commission on April 3, 2012;

	(File No. 000-30109) for its Annual Meeting of Stockholders held on May 17, 2012).
10.21#	Luminex Corporation Employee Stock Purchase Plan (Previously filed as Annex B to the Company's Proxy Statement (filed with the Securities and Exchange Commission on April 3, 2012; (File No. 000-30109) for its Annual Meeting of Stockholders held on May 17, 2012).
10.22#	Form of Amendment to Employment Agreement, effective as of December 31, 2012, by and between Luminex Corporation and its Executives (Previously filed as an Exhibit to the Company's Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2012).
10.23#	Employment Agreement, dated October 14, 2014, between Luminex Corporation and Nachum Shamir (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed October 20, 2014).
10.24#	Employment Agreement, dated August 14, 2012, by and between Luminex Corporation and Nancy M. Fairchild (Previously filed as an Exhibit to the Company’s Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2014).
10.25#	Second Amendment to Employment Agreement, effective as of February 6, 2014, by and between Luminex Corporation and Nancy M. Fairchild (Previously filed as an Exhibit to the Company’s Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2014).

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10.26#	Third Amendment to Employment Agreement, effective as of January 1, 2015, by and between Luminex Corporation and Nancy M. Fairchild (Previously filed as an Exhibit to the Company's Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2014).
10.27#	Omnibus Amendment to the Luminex Corporation Restricted Share Unit Award Agreements (2012 and 2013 LTIPs) (Previously filed as an Exhibit to the Company's Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2014).
10.28#	First Amendment to the Luminex Corporation Second Amended and Restated 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed on March 11, 2015).
10.29#	Form of Non-Qualified Stock Option Agreement for the Luminex Corporation Second Amended and Restated 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended March 31, 2015).
10.30#	Form of Stock Appreciation Rights Agreement for the Luminex Corporation Second Amended and Restated 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended March 31, 2015).
10.31#	Luminex Corporation Third Amended and Restated 2006 Equity Incentive Plan (Previously filed as Annex A to the Company's Proxy Statement (filed with the Securities and Exchange Commission on March 30, 2015; (File No. 000-30109) for its Annual Meeting of Stockholders held on May 14, 2015).
10.32#	Form of Restricted Share Award Agreement for Directors for the Luminex Corporation Third Amended and Restated 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended June 30, 2015).
10.33#	Form of Restricted Share Unit Agreement for Directors for the Luminex Corporation Third Amended and Restated 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended June 30, 2015).
10.34#	Employment Agreement, dated March 4, 2015, by and between Luminex Corporation and Richard Rew (Previously filed as an Exhibit to the Company's Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2015).
10.35#	Employment Agreement, dated March 16, 2015, by and between Luminex Corporation and Randall Myers (Previously filed as an Exhibit to the Company's Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2016).
10.36#	Employment Agreement, dated November 1, 2016, by and between Luminex Corporation and Todd Bennett (Previously filed as an Exhibit to the Company's Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2016).
10.37#	Amended and Restated 2016 Management Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed March 28, 2016).
10.38#	Form of Performance-Based Non-Qualified Stock Option Agreement for the Luminex Corporation Third Amended and Restated 2006 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Quarterly

	Report on Form 10-Q (File No. 000-30109) for the quarterly period ended March 31, 2016).
10.39#	First Amendment to Employment Agreement, effective March 27, 2017, by and between Luminex Corporation and Nachum Shamir (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed March 31, 2017).
10.40#	Amended and Restated 2017 Management Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109), filed March 31, 2017).
10.41#	Amended and Restated Luminex Corporation Employee Stock Purchase Plan (Previously filed as Annex A to the Company's Proxy Statement (filed with the Securities and Exchange Commission on April 3, 2017; (File No. 000-30109) for its Annual Meeting of Stockholders held on May 18, 2017).
10.42#	Employment Agreement, dated January 1, 2018, by and between Luminex Corporation and Chuck Collins (Previously filed as an Exhibit to the Company's Annual Report on Form 10-K (File No. 000-30109) for the fiscal year ended December 31, 2017).
10.43#	Form of Amendment to Employment Agreement by and between Luminex Corporation and its Executives.(Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended March 31, 2018).

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10.44#	Luminex Corporation 2018 Equity Incentive Plan (Previously filed as Annex A to the Company's Proxy Statement (filed with the Securities and Exchange Commission (File No. 000-30109) on April 2, 2018) for its Annual Meeting of Stockholders held on May 17, 2018).
10.45#	Luminex Corporation 2018 Management Incentive Plan (Previously filed as an Exhibit to the Company's Current Report on Form 8-K (File No. 000-30109) filed April 20, 2018).
10.46#	Form of Restricted Share Award Agreement for Directors for the Luminex Corporation 2018 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended June 30, 2018).
10.47#	Form of Restricted Share Unit Agreement for Directors for the Luminex Corporation 2018 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended June 30, 2018).
10.48#	Form of Non-Qualified Stock Option Agreement for the Luminex Corporation 2018 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended June 30, 2018).
10.49#	Form of Restricted Share Award Agreement for Officers and Employees for the Luminex Corporation 2018 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended June 30, 2018).
10.50#	Form of Restricted Share Unit Agreement for Officers and Employees for the Luminex Corporation 2018 Equity Incentive Plan (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended June 30, 2018).
10.51	First Amendment to Lease Agreement between PS Business Parks, L.P., as Landlord, and Luminex Corporation, as Tenant, dated March, 2017 (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended September 30, 2018).
10.52	Second Amendment to Lease Agreement between PS Business Parks, L.P., as Landlord, and Luminex Corporation, as Tenant, dated July, 2018 (Previously filed as an Exhibit to the Company's Quarterly Report on Form 10-Q (File No. 000-30109) for the quarterly period ended September 30, 2018).
10.53#	Employment Agreement, dated March 1, 2018, by and between Luminex Corporation and Eric Shapiro.
21.1	Subsidiaries of the Company.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (incorporated in the signature page of this report).
31.1	Certification by CEO pursuant to Securities and Exchange Act Rules 13a-14(a) and 15d - 14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by CFO pursuant to Securities and Exchange Act Rules 13a-14(a) and 15d - 14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1	Certification by CEO pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by CFO pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Luminex Corporation's Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL: (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Comprehensive Income; (iii) Condensed Consolidated Statements of Cash Flows; and (iv) Notes to Condensed Consolidated Financial Statements.

#Management contract or compensatory plan or arrangement.

*Schedules, annexes and exhibits omitted pursuant to Item 601(b)(2) of Regulation S-K. Luminex agrees to furnish a supplemental copy of omitted schedules to the Securities and Exchange Commission upon request.

ITEM 16. FORM 10-K SUMMARY

None.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

LUMINEX CORPORATION
By: /s/ Nachum Shamir
Nachum Shamir
President and Chief Executive Officer
Date: February 26, 2019

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Nachum Shamir and Harriss T. Currie, each his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURES	TITLE	DATE
/s/ Nachum Shamir Nachum Shamir	President and Chief Executive Officer, Director (Principal Executive Officer)	February 26, 2019
/s/ Harriss T. Currie Harriss T. Currie	Chief Financial Officer, Senior Vice President of Finance (Principal Financial Officer and Principal Accounting Officer)	February 26, 2019
/s/ Robert J. Cresci Robert J. Cresci	Director	February 26, 2019
/s/ Stephen L. Eck Stephen L. Eck	Director	February 26, 2019
/s/ Thomas W. Erickson Thomas W. Erickson	Director	February 26, 2019
/s/ Jim D. Kever	Director	

Jim D. Kever		February 26, 2019
/s/ G. Walter Loewenbaum II G. Walter Loewenbaum II	Chairman of the Board of Directors, Director	February 26, 2019
/s/ Kevin M. McNamara Kevin M. McNamara	Director	February 26, 2019
/s/ Edward A. Ogunro Edward A. Ogunro	Director	February 26, 2019
/s/ Kenneth A. Samet Kenneth A. Samet	Director	February 26, 2019