QUIDEL CORP /DE/
Form 10-K
February 16, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
(Mark One)
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2016
OR
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from N/A to N/A
Commission file number: 0-10961
QUIDEL CORPORATION
(Exact name of registrant as specified in its charter)

DELAWARE	94-2573850
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
12544 High Bluff Drive, Suite 200 San Diego, California	92130
(Address of principal executive offices)	(Zip Code)

858-552-1100
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common stock, $0.001 par value	Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ¨ No x
Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.
(Check One):

Large accelerated filer ¨	Accelerated filer x

Non-accelerated filer ¨(Do not check if a smaller reporting company) Smaller reporting company¨
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x
The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $486,300,707 based on the closing sale price at which the common stock was last sold, as of the last business day of the registrant's most recently completed second fiscal quarter.
As of February 10, 2017, 32,950,618 shares of the registrant's common stock were outstanding.
DOCUMENTS INCORPORATED BY REFERENCE
(To the Extent Indicated Herein)
Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the registrant's 2017 Annual Meeting of Stockholders (to be held on May 16, 2017) are incorporated by reference into Part III, Items 10, 11, 12, 13 and 14 of this Annual Report on Form 10-K

QUIDEL CORPORATION
FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2016
TABLE OF CONTENTS

A Warning About Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, fluctuations in our operating results resulting from seasonality, the timing of the onset, length and severity of cold and flu seasons, government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses, adverse changes in competitive conditions in domestic and international markets, changes in sales levels as it relates to the absorption of our fixed costs, lower than anticipated market penetration of our products, the reimbursement system currently in place and future changes to that system, changes in economic conditions in our domestic and international markets, the quantity of our product in our distributors' inventory or distribution channels, changes in the buying patterns of our distributors, and changes in the healthcare market and consolidation of our customer base; our development and protection of intellectual property; our development of new technologies, products and markets; our reliance on a limited number of key distributors; our reliance on sales of our influenza diagnostics tests; our ability to manage our growth strategy, including our ability to integrate companies or technologies we have acquired or may acquire; intellectual property risks, including but not limited to, infringement litigation; our inability to settle conversions of our Convertible Senior Notes in cash; the effect on our operating results from the trigger of the conditional conversion feature of our Convertible Senior Notes; the possibility that we may incur additional indebtedness; our need for additional funds to finance our operating needs; volatility and disruption in the global capital and credit markets; acceptance of our products among physicians and other healthcare providers; competition with other providers of diagnostic products; adverse actions or delays in new product reviews or related to currently-marketed products by the U.S. Food and Drug Administration (the "FDA"); changes in government policies; compliance with other government regulations, such as safe working conditions, manufacturing practices, environmental protection, fire hazard and disposal of hazardous substances; third-party reimbursement policies; our ability to meet demand for our products; interruptions in our supply of raw materials; product defects; business risks not covered by insurance and exposure to other litigation claims; interruption to our computer systems; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, exposure to currency exchange fluctuations and foreign currency exchange risk sharing arrangements, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, political and economic instability, taxes, and diversion of lower priced international products into U.S. markets; dilution resulting from future sales of our equity; volatility in our stock price; provisions in our charter documents, Delaware law and our Convertible Senior Notes that might delay or impede stockholder actions with respect to business combinations or similar transactions; and our intention of not paying dividends. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," "plan," "intend," "goal," "project," "strategy," "fu words, although some forward-looking statements are expressed differently. Forward-looking statements in this Annual Report include, among others, statements concerning: our outlook for the upcoming fiscal year, projected capital expenditures for the upcoming fiscal year and our source of funds for such expenditures; the sufficiency of our liquidity and capital resources; our strategy, goals, initiatives and objectives; the anticipated beneficial attributes of products and platforms under development; anticipated new product and development results; that we expect to continue to depend on a few key distributors for sales of our products; expected growth and the sources of that growth; the impact of new accounting standards; that point-of-care testing is increasing; that clinical reference laboratories will continue to be a competitive threat; that we will continue to make substantial expenditures for sales and marketing, manufacturing and product research and development activities; that influenza test revenues will continue to be a significant portion of our total revenue; industry consolidation and competition trends; competition for management and key personnel; that we may enter into additional foreign currency exchange risk sharing arrangements; that the price of our common stock will continue to fluctuate; the sufficiency of our insurance and our exposure to claims and litigation; our intention to not pay dividends; that we will continue to obtain licenses from

third parties; and our intention to continue to evaluate technology and acquisition opportunities. The risks described under “Risk Factors” in Item 1A of this Annual Report and elsewhere herein and in reports and registration statements that we file with the Securities and Exchange Commission (the “SEC”) from time to time, should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management’s analysis only as of the date of this Annual Report. Except as required by law, we undertake no obligation to publicly release the results of any revision or update of these forward-looking statements, whether as a result of new information, future events or otherwise.

Part I

Item 1. Business

All references to “we,” “our,” and “us” in this Annual Report refer to Quidel Corporation and its subsidiaries.

Overview

We have a leadership position in the development, manufacturing and marketing of rapid diagnostic testing solutions. These diagnostic testing solutions are separated into our four product categories, including: immunoassays, molecular assays, virology and specialty products. We sell our products directly to end users and distributors, in each case, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, leading universities, retail clinics, pharmacies and wellness screening centers. We market our products in the United States through a network of national and regional distributors, and through a direct sales force. Internationally, we market primarily through distributor arrangements.

We commenced our operations in 1979 and launched our first products, dipstick-based pregnancy tests, in 1983. Since such time, our product base and technology platforms have expanded through internal development and acquisitions of other products, technologies and companies. Our diagnostic solutions aid in the detection and diagnosis of many critical diseases and other medical conditions, including infectious diseases, women’s health, gastrointestinal diseases, autoimmune diseases, bone health and thyroid diseases.

Corporate Information

We are a corporation, originally incorporated as Monoclonal Antibodies, Inc. in California in 1979 and re-incorporated as Quidel Corporation in the State of Delaware in 1987. Our executive offices are located at 12544 High Bluff Drive, Suite 200, San Diego, California 92130, and our telephone number is (858) 552-1100. This Annual Report and each of our other periodic and current reports, including any amendments thereto, are available, free of charge, on our website, www.quidel.com, as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The information contained on our website is not incorporated by reference into this Annual Report and should not be considered part of this Annual Report. In addition, the SEC website contains reports, proxy and information statements, and other information about us at www.sec.gov.

Business Strategy

Our primary objective is to increase shareholder value by building a broader-based diagnostic company capable of delivering revenue growth and consistent operating results. Our strategy is to identify potential market segments that provide, or are expected to provide, significant total market opportunities, and in which we can be successful by applying our significant expertise and know-how to develop differentiated technologies and products.

Our diagnostic testing solutions are designed to provide specialized results that serve a broad range of customers, by addressing the market requirements of ease of use, reduced cost, increased test accuracy and reduced time to result. Our current approach to address this diagnostic continuum relative to our strategy is comprised of the following:

- rapid point-of-care immunoassay tests for use in physician offices, hospital laboratories and emergency departments, retail clinics, pharmacies and other urgent care or alternative site settings;
- direct fluorescent assays (“DFA”) and culture-based tests for the clinical virology laboratory;
- molecular diagnostic tests across a number of laboratory and other segments; and
- specialty products serving the bone health, autoimmune and complement research communities.

Our current focus to accomplish our primary objective includes the following:

- leveraging our current infrastructure to develop and launch new rapid immunoassays such as additional assays for our Sofia® Analyzer and next generation analyzer (Sofia 2);
- developing a molecular diagnostics franchise that incorporates three distinct testing platforms, AmpliVue®, Solana® and Savanna™ and that leverages our molecular assay development competencies; and
-

strengthening our position with distribution partners and our end-user customers to gain more emphasis on our products in the U.S. and abroad.

Our current initiatives to execute this strategy include the following:

- continue to provide products that can compete effectively in the healthcare market where cost is important;
- continue to focus our research and development efforts on three areas:
- new proprietary product platform development;
- the creation of improved products and new products for existing markets and unmet clinical needs; and
- pursuit of collaborations with, or acquisitions of, other companies for new and existing products and markets that advance our differentiated strategy.
- provide clinicians with validated studies that encompass the clinical efficacy and economic efficiency of our diagnostic tests for the professional market;
- strengthen our market and brand leadership in current markets by acquiring and/or developing and introducing clinically superior diagnostic solutions;
- strengthen our direct sales force to enhance relationships with integrated delivery networks, laboratories and hospitals, with a goal of driving growth through improved physician and laboratorian satisfaction;
- leverage our wireless connectivity and data management systems, including cloud-based tools;
- support payer evaluation of diagnostic tests and establishment of favorable reimbursement rates;
- continue to create strong global alliances to support our efforts to achieve leadership in key markets and expand our presence in emerging markets; and
- further refine our manufacturing efficiencies and productivity improvements to improve profit, with continued focus on profitable products and markets and our efforts to leverage our core competency in new product development.

Product development activities are inherently uncertain, and there can be no assurance that we will be able to obtain regulatory body clearance to market any of our products, or if we obtain clearances, that we will successfully commercialize any of our products. In addition, we may terminate our development efforts with respect to one or more of our products under development at any time, including before or during clinical trials.

The Overall Market for In Vitro Diagnostics

Customers for In Vitro Diagnostics ("IVD") products are primarily centralized laboratories and decentralized point-of-care settings.

Centralized testing market

The centralized in vitro diagnostic testing process typically involves obtaining a specimen of blood, urine or other sample from the patient and sending the sample from the healthcare provider's office, hospital unit or clinic to a central laboratory. In a typical visit to the physician's office, after the patient's test specimen is collected, the patient is usually sent home and receives the results of the test several hours or days later. The result of this process is that the patient may leave the physician's office without confirmation of the diagnosis and the opportunity to begin potentially more effective immediate care.

Decentralized POC market

Point-of-care ("POC") testing for certain diseases has become an accepted adjunct to central laboratory and self-testing. The professional POC market is comprised of two general segments: decentralized testing in non-institutional settings, such as physicians' offices, and hospital testing (e.g., emergency rooms and bedside).

- Hospital POC testing is accepted and growing and is generally an extension of the hospital's central laboratory. Hospitals in the U.S. have progressively sought to reduce the length of patient stays and, consequently, the proportion of cases seen as outpatients have increased. If the U.S. experience is representative of future trends, emergency departments and other critical care units such as intensive care units, operating rooms, trauma and cardiac centers are increasingly becoming the principal centers for the management of moderate and severe acute illness.
- Out-of-hospital testing sites consist of physicians' office laboratories, nursing homes, pharmacies, retail clinics and other non-institutional, ambulatory settings in which healthcare providers perform diagnostic tests.

This decentralized POC market encompasses a large variety of IVD products ranging from moderate-sized instrumented diagnostic systems serving larger group practices to single-use, disposable tests. We believe POC testing is increasing due to its clinical benefit, fast results, cost-effectiveness and patient satisfaction.

We believe that the growth in POC testing is in part due to evolving technological improvements creating high quality tests with laboratory accuracy and POC ease-of-use, some of which are capable of being granted a waiver under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA").

Products

We provide diagnostic testing solutions under various brand names, including, among others, the following: Quidel®, QuickVue®, QuickVue+®, Sofia®, AmpliVue®, Solana®, Virena®, MicroVue™, Lyra®, FreshCells™, D3®, FastPoint®, ReadyCells®, Super E-Mix™, ELVIRA®, ELVIS® and Thyretain®.

System Platforms:

Our diagnostic testing solutions are separated into our four product categories: immunoassay, molecular, virology and specialty products. The key platforms are described below:

Immunoassays

Quickvue. Quickvue is the brand name for our rapid, visually-read, lateral flow immunoassay products. We have been a leader in the development and production of high quality lateral flow diagnostics since the early 1990s and offer a broad portfolio of products to diagnose a wide variety of infectious diseases and medical conditions.

Sofia Analyzer. Sofia is the brand name for our fluorescent immunoassay ("FIA") system. The easy-to-use Sofia Analyzer combines unique software, when used in conjunction with Sofia FIA tests, to yield an automatic, objective result that is readily available on the instrument's screen, in a hard-copy printout, and in a transmissible electronic form that can network via a lab information system to hospital and medical center databases. The Sofia FIA tests employ advanced lateral flow and immunofluorescence technologies to provide enhanced performance for several assays as noted in our disease state discussion below. The Sofia Analyzer provides for different operational modes to accommodate both small and large laboratories as well as other features designed to facilitate use in a variety of healthcare settings, including hospitals, medical centers, and small clinics.

Next Generation Analyzer. We are developing the next generation Sofia Analyzer (Sofia 2) with added benefits and features and at a cost point that allows us to better address the lower-volume segment of the diagnostic testing market. We believe users will see an improvement in individual test performance and workflow. Enhanced optics are designed to provide added performance benefits and kinetic reading is designed to enable positive test results to be read in as short as a few minutes. Similar to the original Sofia Analyzer, the next generation analyzer is planned to initially center around respiratory assays and then extend into Lyme Disease and Vitamin D tests.

Molecular

Lyra. Our open system molecular assays run on several thermocyclers currently on the market. We have several existing Lyra Molecular Real-Time Polymerase Chain Reaction ("PCR") assays that provide important benefits to the customer, including, among others, room temperature storage, reduced process time, and ready-to-use reagent configurations. These include several assays as noted in our disease state discussion below.

AmpliVue. With our Molecular AmpliVue hand-held molecular diagnostic assay platform, the detection of the pathogen is achieved using a hand-held, fully contained cassette that combines isothermal Helicase Dependent Amplification ("HDA") with lateral flow detection technology, and is currently used in several assays also noted in our disease state discussion below.

Solana. The Solana system was developed as an extension to the AmpliVue product line, running the same proprietary HDA technology. Solana is an easy to run amplification and detection system that has the ability to concurrently run up to 12 assays at a time.

Savanna. We are developing the Savanna system as a rugged, low-cost, fully-integrated system with novel extraction, and sample in/result out simplicity. The system is expected to be able to run either PCR or HDA assays from multiple sample types.

Virology

Virology. We provide a wide variety of traditional cell lines, specimen collection devices, media and controls for use in laboratories that culture and test for many human viruses, including, among others, respiratory and herpes family viruses. We provide cell-based products under the FreshCells brand in multiple different formats, including tubes, shell vials and multi-well plates. Our Virology product category includes the FDA cleared bioassay Thyretain, which is used for the differential diagnosis of an autoimmune disease called Graves Disease.

Specialty Products

Specialty Products. As a leader in the research space with our biomarkers for bone health, we produce both clinical and research products for the assessment of osteoporosis and the evaluation of bone resorption/formation, which, including our metabolic bone markers, are used by physicians to monitor the effectiveness of therapy in pharmaceutical and related research. In the area of autoimmune disease, we have developed Enzyme Linked Immunosorbent Assay ("ELISA") based assays and reagents for the detection of activation products from the three main complement pathways. Assays are developed on a microwell platform and are currently marketed to clinicians and researchers. We currently sell these products both directly and through select distributors throughout the world under the Quidel and MicroVue brands.

Connectivity and Data Management

Virena. Virena is a wireless cellular data management and surveillance system that operates as a cloud-based solution connecting Quidel instruments across a healthcare system and automatically transmitting de-identified test results to a secure database. With Virena, a health system, physician office laboratory ("POL"), urgent care or retail clinic has the ability to compile, analyze, map and generate reports of de-identified test results improving operational efficiencies, quality and patient outcome initiatives.

Medical and Wellness Categories:

Our products address the following medical and wellness categories:

Infectious Diseases

Influenza. Our Sofia Influenza A+B test, used in conjunction with our Sofia Analyzer, and our QuickVue influenza tests are rapid, qualitative tests for the detection of the viral antigens of influenza type A and B, the two most common types of the influenza virus. In addition, our Sofia Influenza A+B test has special 510(k) clearance for an update to our package insert to include analytical reactivity with an avian Influenza A (H7N9) strain, A/Anhui/1/2013. In addition, Quidel offers molecular testing options with the recently launched Solana Influenza A+B assay utilizing HDA technology and our Lyra Influenza A+B real-time PCR assay.

Streptococci. We offer a variety of products designed to detect various Streptococcal disease states utilizing fluorescent immunoassay, lateral flow and molecular technologies. Our Sofia Strep A fluorescent immunoassay, used in conjunction with our Sofia Analyzer, and our QuickVue Strep A tests are intended for the rapid, qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture. Our Solana Strep Complete and Solana Group A Strep assays allow for the rapid, accurate detection of Group A and pyogenic Group C/G Strep and Group A Strep, respectively, utilizing our molecular HDA technology. In addition, our Lyra Direct Strep Assay is a multiplex real-time PCR assay that detects and differentiates between pyogenic Group A and pyogenic C or G Streptococcal throat infections.

RSV. Our Sofia RSV test and our QuickVue RSV test are rapid immunoassay tests for Respiratory Syncytial Virus ("RSV"). Quidel also offers our combo Quidel Molecular RSV + human metapneumovirus (hMPV) test. The majority of upper respiratory tract infections in children are caused by viruses, and RSV is generally recognized as a frequent agent responsible for these infections.

Herpes and Herpes Family. We offer a variety of products designed to detect various herpes simplex virus ("HSV") and herpes family viruses utilizing molecular and cell culture technologies. In the fall of 2016, we obtained FDA clearance of our Solana HSV-1+2/VZV Assay, used in conjunction with our Solana instrument, for the detection of HSV type 1, HSV type 2, and varicella-zoster virus ("VZV"). We also offer our Lyra Direct HSV 1+2/VZV and AmpliVue HSV 1+2 assays. In addition, our proprietary engineered cell culture system, ELVIS HSV, is an FDA cleared and highly sensitive system for the isolation and detection of HSV types 1 and 2. We also provide a multiplex cell culture solution using a propriety cell platform called H&V-Mix™ that is used to isolate HSV, VZV and Cytomegalovirus,

all in the herpes family of viruses. Antibody detection and identification of each of these viruses can be performed with FDA cleared antibody products provided under the D3 DFA brand. HSV is a widespread sexually transmitted infection. VZV is a DNA virus of the family Herpesviridae; infection results

in chickenpox (varicella) and may lead to complications such as pneumonia and may reactivate later in life to produce shingles.

Multiplex Respiratory. Our cell culture and DFA detection solutions, including D3 FastPoint technology, are used by reference laboratories, public health labs and acute care hospitals to detect eight major viral respiratory pathogens. Our proprietary cell culture platform R-Mix™ combined with our D3 Ultra DFA antibody kit, detects Influenza A and B, RSV, Adenovirus and Parainfluenza types 1, 2 and 3, with turn-around times between 16 and 48 hours. The same D3 Ultra DFA antibody kit can also be used for direct specimen testing for those viruses with turn-around times in less than 90 minutes. Our D3 FastPoint antibody kit detects eight viruses, with human metapneumovirus added to the testing menu, and provides laboratories, in a direct specimen testing format, the ability to produce virus identification in less than 25 minutes from specimen receipt.

S. pneomoniae. Our Sofia S. Pneomoniae FIA, used in conjunction with our Sofia Analyzer, was CE Marked for sale in the European market in 2016. The assay is used to aid in the detection of both pneumococcal pneumonia and pneumococccal menigitis. Streptoccus pneumoniae is a leading cause of community-acquired pneumonia and bacterial meningitis.

Legionella. Our Sofia Legionella FIA, used in conjunction with our Sofia Analyzer, is CE Marked for sale in the European market. The assay is used to aid in the detection of Legionella pneumophila seorgroup 1 antigen, which is the major causative agent of Legionnaires' disease, a disease primarily of pneumonia.

Bordetella Pertussis. In 2014, we received FDA clearance for our AmpliVue Bordetella Assay, used in detection of Bordetella pertussis. Pertussis, or whooping cough, is a very contagious disease of caused by the Bordetella pertussis bacteria and there has been increasing incidence in recent years.

Adenovirus and Parainfluenza. Quidel offers the Lyra Adenovirus Assay, a real-time PCR test for the qualitative detection of human adenovirus (HAdV) viral DNA, and our Lyra Parainfluenza Assay, a real-time PCR test for the qualitative detection and identification of Parainfluenza virus infections for types 1, 2 or 3 viral RNA.

POC Women’s and General Health

Pregnancy. Our Sofia hCG fluorescent immunoassay and our QuickVue pregnancy tests are used for the qualitative detection of hCG in serum or urine for the early detection of pregnancy. The early detection of pregnancy enables the physician and patient to institute proper care, helping to promote the health of both the woman and the developing embryo.

Graves Disease. Our FDA cleared bioassay called Thyretain is used for the differential diagnosis of an autoimmune disease called Graves Disease. Graves Disease is caused by antibodies that stimulate the thyroid hormone receptors to create a hyperthyroid condition causing symptoms that include heart palpitations, unexplained weight loss, anxiety, depression and fatigue. Graves Disease is considered the most common autoimmune disorder in the U.S. according to an article published in the New England Journal of Medicine and it predominantly affects women. Thyretain is sold to reference laboratories and select acute care hospitals and has been successfully deployed on automated testing platforms.

Chlamydia. Our QuickVue Chlamydia test is a lateral flow immunoassay for the rapid, qualitative detection of Chlamydia trachomatis from endocervical swab and cytology brush specimens. The test is intended for use as an aid in the presumptive diagnosis of Chlamydia. Chlamydia trachomatis is responsible for the most widespread sexually transmitted disease in the U.S. Over one-half of infected women do not have symptoms and, if left untreated, Chlamydia trachomatis can cause sterility.

Trichomonas. In 2016, we obtained FDA clearance of our Solana Trichomonas assay, used in conjunction with our Solana instrument, to aid in the diagnosis of trichomoniasis, a sexually transmitted disease attributable to infection from the Trichomonas vaginalis parasite. Trichomoniasis affects millions of people in the U.S., is more common in women and can be treated with antibiotics upon diagnosis.

Bone Health. Osteoporosis is a systemic skeletal disease characterized by low bone mass and deterioration of the microarchitecture of bone tissue, with a consequent increase in bone fragility and susceptibility to fractures. The risk for fracture increases exponentially with age. A key set of parameters in the monitoring of osteoporosis, both before and after therapy, are biochemical markers of bone metabolism. As a leader in the research space with our biomarkers for bone health, we produce both clinical and research products for the assessment of osteoporosis and the evaluation

of bone resorption/formation, which, including our metabolic bone markers, are used by physicians to monitor the effectiveness of therapy in pharmaceutical and related research.

Gastrointestinal Diseases

Clostridium difficile. Our Lyra Direct C. difficile Assay, is a qualitative, multiplexed real-time PCR test for the detection of Clostridium difficile Toxin A or Toxin B genes and is approved for use on a variety of real-time PCR instruments. We also sell our AmpliVue C. difficile Assay, utilizing our HDA technology, for the detection of the Clostridium difficile Toxin A gene.

Clostridium difficile (“C. diff”) is a life threatening bacterial infection, especially for the elderly and patients on a prolonged antibiotic regimen. Currently more than 500,000 cases of C. diff infections are diagnosed each year in the U.S.

Enterovirus. Enteroviruses reproduce initially in the gastrointestinal tract before spreading to other organs such as the nervous system, heart and skin. Enteroviruses can also infect the respiratory tract. Enteroviruses such as Coxsackievirus A16 are referred to as Hand Foot and Mouth disease and commonly affect infants and children. Our indirect fluorescent antibody (“IFA”) products sold under the name Super E-Mix and D3 IFA Enterovirus kit are used by reference laboratories and acute care hospitals.

Immunoassay fecal occult blood. Our QuickVue fecal immunochemical test (“FIT”) is a rapid test intended to detect the presence of blood in stool specimens. Blood in the stool is an indication of a number of gastrointestinal disorders, including colorectal cancer.

Helicobacter pylori (“H. pylori”). H. pylori is the bacterium associated with approximately 80% of patients diagnosed with peptic ulcers in the U.S. H. pylori is implicated in chronic gastritis and is recognized by the World Health Organization as a Class 1 carcinogen that may increase a person’s risk of developing stomach cancer. Our QuickVue rapid test is a serological test that measures antibodies circulating in the blood caused by the immune response to the H. pylori bacterium.

Seasonality

Sales of our infectious disease products are subject to, and significantly affected by, the seasonal demands of the cold and flu seasons, prevalent during the fall and winter. As a result of these seasonal demands, we typically experience lower sales volume in the second and third quarters of the calendar year, and typically have higher sales in the first and fourth quarters of the calendar year. Historically, sales of our infectious disease products have varied from year to year based in large part on the severity, length and timing of the onset of the cold and flu season. For the years ended December 31, 2016, 2015 and 2014, sales of our infectious disease products accounted for 71%, 73% and 71%, respectively, of total revenue.

Research and Development

We continue to focus our research and development efforts on three areas:

- new proprietary product platform development,
- the creation of improved products and new products for existing markets and unmet clinical needs, and
- pursuit of collaborations with, or acquisitions of, other companies for new and existing products and markets that advance our differentiated strategy.

Research and development expenses were approximately $38.7 million, $35.5 million, and $37.9 million for the years ended December 31, 2016, 2015 and 2014, respectively. We anticipate that we will continue to devote a significant amount of financial resources to product and technology research and development for the foreseeable future.

Marketing and Distribution

Our business strategy is designed around serving the continuum of healthcare delivery needs starting with POC clinicians located in small doctor’s office practices to moderately complex POLs through the highly complex environment in hospital and clinical reference laboratories.

Within the inherent operational diversity of these various segments, we focus on ensuring market leadership and providing points of differentiation by specializing in the diagnosis and monitoring of selected disease states. Our marketing strategy includes ensuring that our key product portfolios are supported by clinical validation and health economic and outcomes research that demonstrates to hospitals, laboratories, acute care facilities and POC clinicians that these tests deliver fast, high quality results, are cost-effective to use, and improve patient outcomes.

Our distribution strategy takes into account the fact that the U.S. POC market is highly fragmented, with many small or medium-sized customers. A network of national and regional distributors is utilized, combined with our own sales force, to reach customers using POC diagnostic tests. We have developed priority status with several of the major distributors in the U.S., resulting in many of our products having preferred product status with these distributors.

We have expanded the size of our U.S. sales force in the past few years. As of December 31, 2016, we employed more than 100 U.S. sales representatives. We are utilizing this expanded sales force to work closely with our key distributors to drive market penetration of our products in the U.S. POC market, with a particular focus on addressing

acute care and integrated delivery network customers.

The sales, distribution and service of our cell culture and molecular diagnostic tests are controlled primarily by us. Laboratory end-users in hospitals and clinical reference laboratories utilizing these diagnostic tests are reached through our own direct sales force and technical support services that have specialized training and understanding of the product portfolio.

Internationally, the use of professional rapid POC diagnostic tests, the acceptance of testing outside the central laboratory, the regulatory requirements to sell POC tests and consumer interest in over-the-counter and self-test products, differ considerably from the U.S. Our international sales are significantly lower than domestic sales, largely due to the POC market being more developed in the U.S. relative to the overall IVD market in other countries.

We derive a significant portion of our total revenue from a relatively small number of distributors. Three of our distributors, which are considered to be among the market leaders, collectively accounted for approximately 44%, 48% and 48% of our total revenue for the years ended December 31, 2016, 2015 and 2014, respectively. These distributors were McKesson Corporation, Cardinal Health, Inc., and Fisher Scientific Company ("Fisher").

See Note 7 "Industry and Geographic Information" in the Notes to Consolidated Financial Statements included in this Annual Report.

Manufacturing

We have two primary manufacturing sites. These two sites are in San Diego, California and Athens, Ohio. Our San Diego facility consists of laboratories devoted to tissue culture, cell culture, protein purification and immunochemistry and production areas dedicated to manufacturing and assembly. In the manufacturing process, biological and chemical supplies and equipment are used. Since the year 2000, the San Diego facility has operated under a Quality Management System certified to the International Organization for Standardization ("ISO") 9001 certification. During 2005, we became certified to the ISO 13485:2003 Regulatory Standard as required for medical device manufacturers distributing product within the European Union and other countries. Many of the immunoassay products manufactured in our San Diego facility are packaged and shipped by a local third party.

Our Athens facility consists of a molecular manufacturing laboratory dedicated to the manufacture and assembly of our molecular products, clean rooms (FS-209E Class 1000: ISO Class 6) for the culturing and dispensing of cell cultures under cGMP conditions and laboratories devoted to tissue culture for the production of monoclonal antibodies and the development and manufacture of research and MicroVue products. In the manufacturing process, biological and chemical supplies are used, as well as specialized equipment. The facility is also certified to the ISO 13485:2003 medical device standard. Packaging and shipping logistics are also handled at the facility.

We seek to conduct all of our manufacturing in compliance with the FDA Quality System Regulations ("QSR") (formerly Good Manufacturing Practices) governing the manufacture of medical devices. Our manufacturing facilities have been registered with the FDA and the Department of Health Services of the State of California for our San Diego facility (the "State FDA"), and have passed routine federal and state inspections confirming compliance with the QSR regulatory requirements.

Government Regulation

Regulation in the United States

The testing, manufacture and commercialization of our products are subject to regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. Pursuant to the U.S. Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder, the FDA regulates the preclinical and clinical testing, manufacture, labeling, distribution and promotion of medical devices. Noncompliance with applicable requirements can result in, among other matters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the FDA to grant premarket clearance or premarket approval for devices, withdrawal of marketing clearances or approvals and criminal prosecution. The FDA also has the authority to request a recall, repair, replacement or refund of the cost of any device manufactured or distributed in the U.S. if the device is deemed to be unsafe.

In the U.S., devices are classified into one of three classes (Class I, II or III) on the basis of the controls deemed necessary by the FDA to reasonably ensure their safety and effectiveness. Class I and II devices are subject to general controls including, but not limited to, performance standards, premarket notification ("510(k)") and post market surveillance. Class III devices generally pose the highest risk to the patient and are typically subject to premarket

approval to ensure their safety and effectiveness. Our current products are all Class I or II.

Prior to commercialization in the U.S. market, manufacturers must obtain FDA clearance through a premarket notification or premarket approval process, which can be lengthy, expensive and uncertain. The FDA has been requiring more rigorous demonstration of product performance as part of the 510(k) process, including submission of extensive clinical data. It generally takes from three to six months to obtain clearance but may take longer. A premarket approval application must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the device, typically including the results of clinical investigations, bench tests and reference laboratory studies. In addition, modifications or enhancements for existing products that could significantly affect safety or effectiveness, or constitute a major change in the intended use of the device, will require new submissions to the FDA.

On January 30, 2008, the FDA issued guidance entitled “Guidance for Industry and FDA Staff Recommendation for CLIA waiver applications.” The guidance sets forth new requirements for obtaining a CLIA waiver that are onerous and have increased the time and cost required to obtain a CLIA waiver.

Any devices we manufacture or distribute pursuant to FDA clearance or approvals are subject to continuing regulation by the FDA and certain state agencies, including adherence to QSR relating to testing, control, documentation and other quality assurance requirements. We must also comply with Medical Device Reporting (“MDR”) requirements mandating reporting to the FDA of any incident in which a device may have caused or contributed to a death or serious injury, or in which a device malfunctioned and, if the malfunction were to recur, would be likely to cause or contribute to a death or serious injury. Labeling and promotional activities are also subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses.

Regulation Outside of the United States

For marketing outside the U.S., we are subject to foreign regulatory requirements governing human clinical testing and marketing approval for our products. These requirements vary by jurisdiction, differ from those in the U.S., and may require us to perform additional or different preclinical or clinical testing regardless of whether we have obtained FDA approval. The amount of time required to obtain necessary approvals may be longer or shorter than that required for FDA approval. In many foreign countries, pricing and reimbursement approvals are also required.

Our initial focus for obtaining marketing approval outside the U.S. is typically the European Union (the “EU”), Japan and China. EU Regulations and Directives generally classify healthcare products either as medicinal products, medical devices or in vitro diagnostics. The CE Mark certification for the EU requires us to receive ISO certification for the manufacture of our products. This certification comes only after the development of an all-inclusive quality system, which is reviewed for compliance with ISO standards by a licensed body working within the EU. After certification is received, a technical file is developed which attests to the product’s compliance with EU directive 98/79/EC for in vitro diagnostic medical devices. Only after this point is the product CE marked. Japanese regulations require registration of in vitro diagnostic products with the Japanese Ministry of Health, Labor and Welfare. Chinese regulations require registration of diagnostic products with the China FDA, or CFDA. Additional clinical trials are typically required for registration purposes. For products marketed in Canada, registration is required with Health Canada and we have our independent party certification under the Canadian Medical Device Regulation.

Intellectual Property

The healthcare industry has traditionally placed considerable importance on obtaining and maintaining patent and trade secret protection for commercially relevant technologies, devices, products and processes. We and other companies engaged in research and development of new diagnostic products actively pursue patents for technologies that are considered novel and patentable. However, important factors, many of which are not within our control, can affect whether and to what extent patent protection in the U.S. and in other important markets worldwide is obtained. By way of example, the speed, accuracy and consistency in application of the law in a patent office within any particular jurisdiction is beyond our control and can be unpredictable. The resolution of issues such as these and their effect upon our long-term success is likewise indeterminable. We have issued patents, both in the U.S. and internationally, with expiration dates ranging from the present through approximately 2034 and have patent applications pending throughout the world.

It has been our policy to file for patent protection in the U.S. and other countries with significant markets, such as Western European countries and Japan, if the economics are deemed to justify such filing and our patent counsel advises that relevant patent protection may be obtained.

A large number of individuals and commercial enterprises seek patent protection for technologies, products and processes in fields in, or related to, our areas of product development. To the extent such efforts are successful, we may be required to obtain licenses and pay significant royalties in order to exploit certain of our product strategies and avoid a material adverse effect on our business. Licenses may not be available to us at all or, if so available, may not be available on acceptable terms.

We are aware of certain patents issued to various developers of diagnostic products with potential applicability to our diagnostic technology. We have licensed certain rights from certain companies to assist with the manufacturing of certain products. In the future, we expect that we will require or desire additional licenses from other parties in order to refine our products further and to allow us to develop, manufacture and market commercially viable or superior products effectively.

We seek to protect our trade secrets and technology by entering into confidentiality agreements with employees and third parties (such as potential licensees, customers, strategic partners and consultants). In addition, we have implemented certain security measures in our laboratories and offices. Also, to the extent that consultants or contracting parties apply technical or scientific information independently developed by them to our projects, disputes may arise as to the proprietary rights to such data.

Under many of our contractual agreements, we have agreed to indemnify the counterparty against costs and liabilities arising out of any patent infringement claims and other intellectual property claims asserted by a third party relating to products sold under those agreements.

Competition

Competition in the development and marketing of IVD products is intense, and innovation, product development, regulatory clearance to market and commercial introduction of new IVD technologies can occur rapidly. We believe that some of the most significant competitive factors in the rapid diagnostic market include convenience, speed to result, specimen flexibility, product menu, clinical needs, price, reimbursement and product performance as well as effective distribution, advertising, promotion and brand name recognition. The competitive factors in the central laboratory market are also significant and include price, product performance, reimbursement, compatibility with routine specimen procurement methods, and manufacturing products in testing formats that meet the workflow demands of larger volume laboratories. We believe our success will depend on our ability to remain abreast of technological advances, to develop, gain regulatory clearance and introduce technologically advanced products, to effectively market to customers a differentiated value proposition represented by our commercialized products, to maintain our brand strength and to attract and retain experienced personnel. The majority of diagnostic tests requested by physicians and other healthcare providers are performed by independent clinical reference laboratories. These laboratories, we expect, will continue to compete vigorously to maintain their dominance of the testing market. In order to achieve market acceptance for our products, we will be required to continue to demonstrate that our products provide physicians and central laboratories cost-effective and time-saving alternatives to competitive products and technologies.

Many of our current and prospective commercial competitors, including several large pharmaceutical and diversified healthcare companies, have substantially greater financial, marketing and other resources than we have. These competitors include, among others, Alere Inc. (“Alere”), Beckman Coulter Primary Care Diagnostics, Fisher, Becton Dickinson and Company, Meridian Bioscience, Inc., Danaher Corporation and Chemicon International, Inc. We also face competition from our distributors since some have created, and others may decide to create, their own products to compete with ours. Competition may also be provided from large, medium and small development companies whose portfolio and technologies are dedicated to the development of diagnostic solutions in areas in which we currently have relevant market share.

Human Resources

As of December 31, 2016, we had 627 employees, none of whom are represented by a labor union. We have experienced no work stoppages and believe that our employee relations are good.

Executive Officers of Quidel Corporation

The names, ages and positions of all executive officers as of December 31, 2016 are listed below, followed by a brief account of their business experience. There are no family relationships among these officers, nor any arrangements or

understandings between any officer and any other person pursuant to which an officer was selected.

Douglas C. Bryant, 59, was named President, Chief Executive Officer and a member of the Board of Directors in February 2009. Mr. Bryant's appointment as President and Chief Executive Officer was effective on March 1, 2009. Prior to

joining us, Mr. Bryant served as Executive Vice President and Chief Operating Officer at Luminex Corporation, managing its Bioscience Group, Luminex Molecular Diagnostics (Toronto), manufacturing, R&D, technical operations, and commercial operations. From 1983 to 2007, Mr. Bryant held various worldwide commercial operations positions with Abbott Laboratories including, among others: Vice President of Abbott Vascular for Asia/Japan, Vice President of Abbott Molecular Global Commercial Operations and Vice President of Abbott Diagnostics Global Commercial Operations. Earlier in his career with Abbott, Mr. Bryant was Vice President of Diagnostic Operations in Europe, the Middle East and Africa, and Vice President of Diagnostic Operations Asia Pacific. Mr. Bryant has over 30 years of industry experience in sales and marketing, product development, manufacturing and service and support in both the diagnostics and life sciences markets. Mr. Bryant holds a B.A. in Economics from the University of California at Davis.

Randall J. Steward, 62, became our Chief Financial Officer in October 2011. Prior to joining us, Mr. Steward served as the Chief Financial Officer for Navilyst Medical, Inc, a medical device company based in Massachusetts. From 2008 to January 2011, Mr. Steward served as Chief Operating Officer for SeQual Technologies, Inc., a San Diego-based medical device company, where he was responsible for all aspects of engineering, manufacturing, finance, and information systems. Prior to SeQual Technologies, Mr. Steward spent 11 years with Spectrum Brands as Executive Vice President and Chief Financial Officer. Mr. Steward holds a B.B.A. in Accounting from Southern Methodist University. He is also a Certified Public Accountant and a member of the American Institute of Certified Public Accountants.

Michael D. Abney, Jr., 53, became our Senior Vice President, Distribution in January 2015. Prior to joining us, he served as Vice President, Channel and Distribution for ConvaTec from 2013 to 2014 and held a number of positions at PSS World Medical, Inc. from 1989 to 2013, including most recently as Vice President, Supplier Management. Mr. Abney received his B.A. degree in Finance from the University of Florida in 1989.

Robert J. Bujarski, J.D., 48, became our Senior Vice President, General Counsel and Corporate Secretary in June 2008 and in 2010 became our Senior Vice President, Business Development, General Counsel and Corporate Secretary. Mr. Bujarski previously served as our Senior Vice President, General Counsel and Corporate Secretary from March 2007 through March 2008. From July 2005 to March 2007, he was our General Counsel and Vice President.

Mr. Bujarski was an associate attorney with the law firm of Gibson, Dunn & Crutcher LLP in its transactions practice group from October 2001 to July 2005. Mr. Bujarski received his B.A. degree in 1991 and his law degree in 2001 from the University of Arizona.

Werner Kroll, Ph.D., 60, became our Senior Vice President, R&D in May 2014. Prior to joining us, Dr. Kroll was Vice President and Global Head Research and Innovation for Novartis Molecular since 2009. Prior to holding that position he held a variety of senior positions from 2005 to 2009 at Novartis. Dr. Kroll has also held senior positions at Bayer from 1991 to 2005. Dr. Kroll received his Ph.D. and a Diploma in Chemistry from the University of Marburg.

Edward K. Russell, 49, became our Senior Vice President, Global Commercial Operations in October 2015. Prior to joining the Company, Mr. Russell was employed by Thermo Fisher Scientific, a life sciences company based in Massachusetts, and its predecessor company Life Technologies for ten years. Mr. Russell served in various leadership roles from 2005 through 2015, including North America Commercial Leader of the BioSciences Division, General Manager of Life Technologies' Global Services & Support Division, and President of Life Technologies Japan. Prior to joining Life Technologies in 2005, Mr. Russell held various leadership positions at FedEx Kinko's, ExxonMobil and Toyota/Lexus. Mr. Russell started his career as an officer in the U.S. Coast Guard. Mr. Russell holds a B.S. in Civil Engineering from the U.S. Coast Guard Academy and an MBA from The Wharton School, University of Pennsylvania.

Item 1A. Risk Factors

Risks Related to Our Business

Our operating results are heavily dependent on sales of our influenza diagnostic tests.

Although we continue to diversify our products, a significant percentage of our total revenues still continue to come from a limited number of our product families. In particular, revenues from the sale of our influenza tests represent a significant portion of our total revenues and are expected to remain so for at least the near future. In addition, the gross margins derived from sales of our influenza tests are significantly higher than the gross margins from many of our other core products. As a result, if sales or revenues of our influenza tests decline for any reason whether as a result of market share loss or price pressure, obsolescence, a mild flu season, regulatory matters or any other reason our operating results would be materially and adversely affected on a disproportionate basis. For the years ended December 31, 2016, 2015 and 2014, sales of our infectious disease products (including influenza test sales) accounted for 71%, 73%, and 71% respectively, of total revenue.

Our operating results may fluctuate adversely as a result of many factors that are outside our control, which may negatively impact our stock price.

Fluctuations in our operating results, for any reason, could cause our growth or operating results to fall below the expectations of investors and securities analysts.

We base the scope of our operations and related expenses on our estimates of future revenues. A significant portion of our operating expenses are fixed, and we may not be able to rapidly adjust our expenses if our revenues fall short of our expectations. Our revenue estimates for future periods are based, among other factors, on estimated end-user demand for our products. If end-user consumption is less than estimated, revenues from our distribution partners and other distribution channels would be expected to fall short of expectations, and because such a significant portion of our costs are fixed, could result in operating losses.

Factors that are beyond our control and that could affect our operating results in the future include:

- timing of the onset, length and severity of the cold and flu seasons;
- seasonal fluctuations in our sales of infectious disease tests, which are generally highest in fall and winter, thus resulting in generally lower operating results in the second and third calendar quarters and higher operating results in the first and fourth calendar quarters;
- government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses, such as H1N1 and avian flu;
- changes in the level of competition, such as would occur if one of our competitors introduced a new, better performing or lower priced product to compete with one or more of our products;
- changes in the reimbursement systems or reimbursement amounts that end-users may rely upon in choosing to use our products;
- changes in economic conditions in our domestic and international markets, such as economic downturns, decreased healthcare spending, reduced consumer demand, inflation and currency fluctuations; changes in government laws and regulations affecting our business;
- lower than anticipated market penetration of our new or more recently introduced products;
- significant quantities of our product or that of our competitors in our distributors' inventories or distribution channels;
- changes in distributor buying patterns; and
- changes in the healthcare market including consolidation in our customer base.

To remain competitive, we must continue to develop, obtain and protect our proprietary technology rights; otherwise, we may lose market share or need to reduce prices as a result of competitors selling technologically superior products that compete with our products.

Our ability to compete successfully in the diagnostic market depends on continued development and introduction of new proprietary technology and the improvement of existing technology. If we cannot continue to improve upon or develop, obtain and protect proprietary technology, our operating results could be adversely affected.

Our competitive position is heavily dependent on obtaining and protecting our own proprietary technology or obtaining licenses from others. Our ability to obtain patents and licenses, and their benefits, is uncertain.

- We have issued patents both in the U.S. and internationally, with expiration dates ranging from the present through approximately 2034. In addition to our patents in the U.S., we have patents issued in various other countries including, among others, Australia, Canada, Japan and various European countries, including France, Germany, Italy, Spain and the United Kingdom. Additionally, we have patent applications pending in the U.S. and various foreign jurisdictions. These pending patent applications may not result in the issuance of any patents, or if issued, may not have priority over others' applications or may not offer meaningful protection against competitors with similar technology or may not otherwise provide commercial value. Moreover, any patents issued to us may be challenged, invalidated, found unenforceable or circumvented in the future. Third parties can make, use and sell products covered by our patents in any country in which we do not have patent protection.
- We also license the right to use our products to our customers under label licenses that are for research purposes only. These licenses could be contested and, because we cannot monitor all potential unauthorized uses of our products around the world, we might not be aware of an unauthorized use or might not be able to enforce the license restrictions in a cost-effective manner.
- Our current and future licenses may not be adequate for the operation of our business. In the future, we expect that we will require or desire additional licenses from other parties in order to refine our products further and to allow us to develop, manufacture and market commercially viable or superior products. We may not be able to obtain licenses for technology patented by others and required to produce our products on commercially reasonable terms, if at all.
- To protect or enforce our patent rights, it may be necessary for us to initiate patent litigation proceedings against third parties, such as infringement suits or interference proceedings. These lawsuits would be expensive, take significant time and would divert management's attention from other business concerns. In the event that we seek to enforce any of our patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, and our patent applications at risk of not being issued. Further, these lawsuits may provoke the defendants to assert claims against us. If we pursue any such claim, we cannot assure you that we will prevail in any of such suits or proceedings or that the damages or other remedies awarded to us, if any, will be economically valuable.
- In addition to our patents, we rely on confidentiality agreements and other similar arrangements with our employees and other persons who have access to our proprietary and confidential information, together with trade secrets and other common law rights, to protect our proprietary and confidential technology. These agreements and laws may not provide meaningful protection for our proprietary technology in the event of unauthorized use or disclosure of such information or in the event that our competitors independently develop technologies that are substantially equivalent or superior to ours. Moreover, the laws of some foreign jurisdictions may not protect intellectual property rights to the same extent as those in the U.S. In the event of unauthorized use or disclosure of such information, if we encounter difficulties or are otherwise unable to effectively protect our intellectual property rights domestically or in foreign jurisdictions, our business, operating results and financial condition could be materially and adversely affected.

In order to remain competitive and profitable, we must expend considerable resources to research new technologies and products and develop new markets, and there is no assurance our efforts to develop new technologies, products or markets will be successful or such technologies, products or markets will be commercially viable.

We devote a significant amount of financial and other resources to researching and developing new technologies, new products and new markets. The development, manufacture and sale of diagnostic products requires a significant investment of resources. The development of new markets also requires a substantial investment of resources, such as new employees, offices and manufacturing facilities. No assurances can be given that our efforts to develop new technologies or products will be successful, that such technologies and products will be commercially viable, or our expansion into new markets will be profitable.

We expect to incur significant operating expenses as a result of continued investment in sales and marketing activities, manufacturing scale-up and new product development associated with our efforts to accomplish our business strategies discussed in "Business - Business Strategy" in Part I of this Annual Report. No assurance can be given that we

will be successful in implementing our operational, growth and other strategic efforts. In addition, the funds for our strategic development projects have in the past come primarily from our business operations, borrowings under available lines of credit and the sale of equity or debt securities. If our business slows and we become less profitable, and as a result have less money

available to fund research and development, we may have to reduce or eliminate programs. Similarly, if adequate financial, personnel, equipment or other resources are not available, we may be required to delay or scale back our strategic efforts.

Our operations will be adversely affected if our operating results do not correspondingly increase with our increased expenditures or if our technology, product and market development efforts are unsuccessful or delayed. Furthermore, our failure to successfully introduce new technologies or products and develop new markets could have a material adverse effect on our business and prospects.

We rely on a limited number of key distributors that account for a substantial majority of our total revenue. The loss of any key distributor or an unsuccessful effort by us to directly distribute our products could lead to reduced sales. Although we have many distributor relationships in the U.S., the market is dominated by a small number of these distributors. Three of our distributors, which are considered to be among the market leaders, collectively accounted (each individually in excess of 10%) for approximately 44%, 48%, and 48% of our total revenue for the years ended December 31, 2016, 2015 and 2014, respectively. In addition, we rely on a few key distributors for a majority of our international sales, and expect to continue to do so for the foreseeable future. The loss or termination of our relationship with any of these key distributors could significantly disrupt our business unless suitable alternatives are timely found or lost sales to one distributor are absorbed by another distributor. Finding a suitable alternative to a lost or terminated distributor may pose challenges in our industry's competitive environment, and another suitable distributor may not be found on satisfactory terms, if at all. For instance, some distributors already have exclusive arrangements with our competitors, and others do not have the same level of penetration into our target markets as our existing distributors. If total revenue from these or any of our other significant distributors were to decrease in any material amount in the future or we are not successful in timely transitioning business to new distributors, our business, operating results and financial condition could be materially and adversely affected.

If we are not able to manage our growth strategy or if we experience difficulties identifying or integrating companies or technologies we may acquire, our operating results may be adversely affected.

Our business strategy contemplates further growth, which would likely result in expanding the scope of operating and financial systems and the geographical area of our operations, including further expansion outside the U.S., as new products and technologies are developed and commercialized or new geographical markets are entered. Because we have a relatively small executive staff, acquisitions and other future growth may divert management's attention from other aspects of our business, and place a strain on existing management and our operational, financial and management information systems. Furthermore, we may expand into markets in which we have less experience or incur higher costs. Some of our growth is expected to come from acquisitions of businesses and technologies. However, we cannot be certain that we will be able to identify attractive acquisition targets, obtain financing for acquisitions on satisfactory terms or successfully acquire identified targets. Additionally, we may experience difficulties integrating the operations of companies or technologies that we may acquire, with our own operations, and we may not realize our anticipated benefits and cost savings within our expected time frame, or at all. We can give no assurance that we will be able to successfully identify, complete and integrate strategic acquisitions. Should we encounter difficulties in managing these tasks and risks, our growth strategy may suffer and our revenue and profitability could be adversely affected.

Intellectual property risks and third-party claims of infringement, misappropriation of proprietary rights or other claims against us could adversely affect our ability to market our products, require us to redesign our products or attempt to seek licenses from third parties, and materially adversely affect our operating results. In addition, the defense of such claims could result in significant costs and divert the attention of our management and other key employees.

Companies in or related to our industry often aggressively protect and pursue their intellectual property rights. There are often intellectual property risks associated with developing and producing new products and entering new markets, and we may not be able to obtain, at reasonable cost or upon commercially reasonable terms, if at all, licenses to intellectual property of others that is alleged to be part of such new or existing products. From time to time, we have received, and may continue to receive, notices that claim we have infringed upon, misappropriated or misused other

parties' proprietary rights.

We have hired and will continue to hire individuals or contractors who have experience in medical diagnostics and these individuals or contractors may have confidential trade secret or proprietary information of third parties. We cannot assure you that these individuals or contractors will not use this third-party information in connection with performing services for us or otherwise reveal this third-party information to us. Thus, we could be sued for misappropriation of proprietary information and trade secrets. Such claims are expensive to defend and could divert our attention and result in substantial damage awards and injunctions that could have a material adverse effect on our business, financial condition or results of operations. In addition, to

the extent that individuals or contractors apply technical or scientific information independently developed by them to our projects, disputes may arise as to the proprietary rights to such data and may result in litigation.

Moreover, in the past we have been engaged in litigation with parties that claim, among other matters, that we infringed their patents. The defense and prosecution of patent and trade secret claims are both costly and time consuming. We or our customers may be sued by other parties that claim that our products have infringed their patents or misappropriated their proprietary rights or that may seek to invalidate one or more of our patents. An adverse determination in any of these types of disputes could prevent us from manufacturing or selling some of our products, limit or restrict the type of work that employees involved with such products may perform for us, increase our costs and expose us to significant liability.

As a general matter, our involvement in litigation or in any claims to determine proprietary rights, as may arise from time to time, could materially and adversely affect our business, financial condition and results of operations for reasons such as:

- pending litigation may of itself cause our distributors or end-users to reduce or terminate purchases of our products;
- it may consume a substantial portion of our managerial and financial resources;
- its outcome would be uncertain and a court may find any third-party patent claims valid and infringed by our products (issuing a preliminary or permanent injunction) that would require us to procure costly licensing arrangements from third parties or withdraw or recall such products from the market, redesign such products offered for sale or under development or restrict employees from performing work in their areas of expertise;
- governmental agencies may commence investigations or criminal proceedings against our employees, former employees and us relating to claims of misappropriation or misuse of another party’s proprietary rights;
- an adverse outcome could subject us to significant liability in the form of past royalty payments, penalties, special and punitive damages, the opposing party’s attorneys' fees, and future royalty payments significantly affecting our future earnings; and
- failure to obtain a necessary license (upon commercially reasonable terms, if at all) upon an adverse outcome could prevent us from selling our current products or other products we may develop.

Even if licenses to intellectual property rights are available, they can be costly. We have entered into various licensing agreements, which largely require payments based on specified product sales as well as the achievement of specific milestones. Royalty and license expenses under these arrangements collectively totaled $0.8 million, $1.1 million and $8.9 million for the years ended December 31, 2016, 2015 and 2014, respectively.

In addition to the foregoing, we may also be required to indemnify some customers, distributors and strategic partners under our agreements with such parties if a third party alleges or if a court finds that our products or activities have infringed upon, misappropriated or misused another person’s proprietary rights. Further, our products may contain technology provided to us by other parties such as contractors, suppliers or customers. We may have little or no ability to determine in advance whether such technology infringes the intellectual property rights of a third party. Our contractors, suppliers and licensors may not be required or financially able to indemnify us in the event that a claim of infringement is asserted against us, or they may be required to indemnify us only up to a maximum amount, above which we would be responsible for any further costs or damages.

We may not have the ability to raise the funds necessary to settle conversions of our Convertible Senior Notes, purchase the Convertible Senior Notes as required upon a fundamental change or service or repay the Convertible Notes at maturity, and potential future debt may contain limitations on our ability to pay cash upon conversion or purchase of our Convertible Senior Notes.

Following a fundamental change (as defined in the indenture to our Convertible Senior Notes), the holders of our Convertible Senior Notes will have the right to require us to purchase their notes for cash. In addition, upon conversion of the Convertible Senior Notes, unless we settle our conversion obligation solely in shares of our common stock (other than cash in lieu of any fractional share), we will be required to make cash payments in respect of the Convertible Senior Notes being surrendered for conversion. We may not have sufficient financial resources, or be able to arrange financing, to pay the fundamental change purchase price in cash with respect to any Convertible Senior Notes surrendered by holders for purchase upon a fundamental change or make cash payments upon conversions. Our failure to purchase the Convertible Senior Notes upon a fundamental change or make cash payments upon conversions

thereof when required would result in an event of default with respect to the Convertible Senior Notes which could, in turn, constitute a default under the terms of our other then-existing indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods,

we may not have sufficient funds to repay the indebtedness and purchase the Convertible Senior Notes or make cash payments upon conversions thereof.

In addition, our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service or repay our debt. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as reducing capital expenditures, selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

The conditional conversion feature of our Convertible Senior Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the Convertible Senior Notes is triggered, holders of Convertible Senior Notes will be entitled to convert their Convertible Senior Notes at any time during specified periods at their option. If one or more Convertible Senior Note holders elects to convert their notes, unless we satisfy our conversion obligation by delivering solely shares of our common stock, we would be required to settle all or a portion of our conversion obligation through the payment of cash, which could adversely affect our liquidity. Furthermore, even if Convertible Senior Note holders did not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Senior Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

We will continue to have the ability to incur debt and our levels of debt may affect our operations and our ability to pay the principal of and interest on our debt.

We and our subsidiaries may be able to incur substantial additional debt in the future. Our indebtedness could be costly or have adverse consequences, such as:

- requiring us to dedicate a substantial portion of our cash flows from operations to payments on our debt;
- limiting our ability to obtain future financing for working capital, capital expenditures, acquisitions, debt obligations and other general corporate requirements;
- making us more vulnerable to adverse conditions in the general economy or our industry and to fluctuations in our operating results, including affecting our ability to comply with and maintain any financial tests and ratios required under our indebtedness;
- limiting our flexibility to engage in certain transactions or to plan for, or react to, changes in our business and the diagnostics industry;
- putting us at a disadvantage compared to competitors that have less relative and/or less restrictive debt; and
- subjecting us to additional restrictive financial and other covenants.

If we incur substantial additional indebtedness in the future, these higher levels of indebtedness may affect our ability to pay the principal of and interest on existing indebtedness and our creditworthiness generally.

We may need to raise additional funds to finance our future capital or operating needs, which could have adverse consequences on our operations and the interests of our stockholders.

Seasonal fluctuations in our operating results could limit the cash we have available for research and development and other operating needs. As a result, we may need to seek to raise funds through public or private debt or sale of equity to achieve our business strategy. In addition, we may need funds to complete acquisitions, or may issue equity in connection with acquisitions. If we raise funds or acquire other technologies or businesses through issuance of equity, this could dilute the interests of our stockholders. Moreover, the availability of additional capital, whether debt or equity from private capital sources (including banks) or the public capital markets, fluctuates as our financial condition and industry or market conditions in general change. There may be times when the private capital markets and the public debt or equity markets lack sufficient liquidity or when our securities cannot be sold at attractive prices, in which case we would not be able to access capital from these sources on favorable terms, if at all. We can give no assurance as to the terms or availability of additional capital.

18

Our results of operations and financial conditions may be adversely affected by the financial soundness of our customers and suppliers.

If our customers' or suppliers' operating and financial performance deteriorates, or if they are unable to make scheduled payments or obtain credit, our customers may not be able to pay, or may delay payment of, accounts receivable owed to us, and our suppliers may restrict credit or impose different payment terms or reduce or terminate production of products they supply to us. Any inability of customers to pay us for our products and services, or any demands by suppliers for different payment terms, may adversely affect our operating results and financial condition. Additionally, both state and federal government sponsored and private payers, as a result of budget deficits or reductions, may seek to reduce their healthcare expenditures by renegotiating their contracts with us. Any reduction in payments by such government sponsored or private payers may adversely affect our earnings and cash flow. Declining economic conditions may also increase our costs.

We may not achieve market acceptance of our products among healthcare providers and physicians, and this would have a negative effect on future sales.

A large part of our business is based on the sale of rapid POC diagnostic tests. Our future sales depend on, among other matters, capture of sales from central laboratories by achieving market acceptance of POC testing from physicians and other healthcare providers. If we do not capture sales at the levels anticipated in our budget, our total revenue will not be at the levels that we expect and the costs we incur or have incurred will be disproportionate to our sales levels. We expect that clinical reference and hospital-based laboratories will continue to compete vigorously against our POC diagnostic products in order to maintain and expand their existing dominance of the overall diagnostic testing market. Moreover, even if we can demonstrate that our products are more cost-effective, save time, or have better performance, physicians and other healthcare providers may resist changing to POC tests. We also believe that adoption of some of our products may be faster if the products are granted a CLIA waiver. On January 30, 2008, the FDA issued guidance setting forth new requirements for obtaining a CLIA waiver that are onerous and have increased the time and cost required to obtain a CLIA waiver. Our failure to achieve market acceptance from physicians and healthcare providers with respect to the use of our POC diagnostic products would have a negative effect on our future sales.

The industry and market segment in which we operate are highly competitive, and intense competition with other providers of diagnostic products may reduce our sales and margins.

Our diagnostic tests compete with similar products made by our competitors. There are a large number of multinational and regional competitors making investments in competing technologies and products, including several large pharmaceutical and diversified healthcare companies. We also face competition from our distributors as some have created, and others may decide to create, their own products to compete with ours. A number of our competitors have a potential competitive advantage because they have substantially greater financial, technical, research and other resources, and larger, more established marketing, sales, distribution and service organizations than we have. Moreover, some competitors offer broader product lines and have greater name recognition than we have. If our competitors' products are more effective than ours or take market share from our products through more effective marketing or competitive pricing, our operating results could be materially and adversely affected.

In addition, there has been a trend toward industry consolidation in our markets over the last few years. We may not be able to compete successfully in an increasingly consolidated industry. We expect this trend toward industry consolidation may continue as companies attempt to strengthen or hold their market positions in an evolving industry and as companies are acquired or are unable to continue operations.

Our business and products are highly regulated by various governmental agencies. Our results of operations would be negatively affected by failures or delays in the receipt of regulatory approvals or clearances, the loss of previously received approvals or other changes to the existing laws and regulations that adversely impact our ability to manufacture and market our products.

The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities in the U.S., principally the FDA and corresponding state and foreign regulatory agencies. The FDA regulates most of our products, which are currently all Class I or II devices. The U.S. Department of Agriculture regulates our veterinary products. Our future performance depends on, among other matters, if, when and at what cost we will receive

regulatory approval for new products. Regulatory review can be a lengthy, expensive and uncertain process, making the timing and costs of clearances and approvals difficult to predict. In addition, certain of our foreign product registrations are owned or controlled by our international distribution partners, such that any change in our arrangement with such partners could result in the loss of or delay in transfer of any such product registrations, thereby interrupting our ability to sell our products in those markets. Our results of operations would be negatively affected by failures or delays in the receipt of regulatory approvals or clearances, the loss of previously

received approvals or clearances or the placement of limits on the marketing and use of our products. For example, the FDA has recently reclassified rapid influenza detection devices from Class I to Class II devices effective February 13, 2017. If such reclassifications affect our ability to market one or more of our rapid influenza products, our total revenue may be negatively affected. Furthermore, in the ordinary course of business, we must frequently make subjective judgments with respect to compliance with applicable laws and regulations. If regulators subsequently disagree with the manner in which we have sought to comply with these regulations, we could be subjected to substantial civil and criminal penalties, as well as field corrective actions, product recall, seizure or injunction with respect to the sale of our products. The assessment of any civil and criminal penalties against us could severely impair our reputation within the industry and affect our operating results, and any limitation on our ability to manufacture and market our products could also have a material adverse effect on our business.

Changes in government policy could adversely affect our business and profitability.

Changes in government policy could have a significant impact on our business by increasing the cost of doing business, affecting our ability to sell our products and negatively impacting our profitability. Such changes could include modifications to existing legislation, such as U.S. tax policy, or entirely new legislation, such as the Affordable Healthcare Act ("AHA") in the U.S. Although we cannot fully predict the many ways that healthcare reform might affect our business, the AHA imposed a 2.3% medical device excise tax ("MDET") on certain transactions, including many U.S. sales of medical devices, which includes the majority of our US product sales. This tax took effect January 1, 2013. For the year ended December 31, 2015, we incurred $2.1 million related to the MDET, and although the MDET was suspended for 2016 and 2017, it may be reinstated in 2018 or beyond. It is unclear whether and to what extent, if at all, other anticipated developments, including changes due to new presidential administration priorities, or changes resulting from healthcare reform, such as a change in the number of people with health insurance, may impact us.

We are subject to numerous government regulations in addition to FDA regulation, and compliance with laws, including changed or new laws, could increase our costs and adversely affect our operations.

In addition to FDA and other regulations referred to above, numerous laws relating to such matters as safe working conditions, manufacturing practices, data privacy, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances impact our business operations. If these laws or their interpretation change or new laws regulating any of our businesses are adopted, the costs of compliance with these laws could substantially increase our overall costs. Failure to comply with any laws, including laws regulating the manufacture and marketing of our products, could result in substantial costs and loss of sales or customers. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our operations, it is impossible to reliably predict the full nature and impact of future legislation or regulatory developments relating to our industry and our products. To the extent the costs and procedures associated with meeting new or changing requirements are substantial, our business, results of operations and financial condition could be adversely affected.

We use hazardous materials in our business that may result in unexpected and substantial claims against us relating to handling, storage or disposal.

Our research and development and manufacturing activities involve the controlled use of hazardous materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. These regulations include federal statutes commonly known as CERCLA, RCRA and the Clean Water Act. Compliance with these laws and regulations is already expensive. If any governmental authorities were to impose new environmental regulations requiring compliance in addition to that required by existing regulations, or alter their interpretation of the requirements of such existing regulations, such environmental regulations could impair our research, development or production efforts by imposing additional, and possibly substantial, costs, restrictions or compliance procedures on our business. In addition, because of the nature of the penalties provided for in some of these environmental regulations, we could be required to pay sizable fines, penalties or damages in the event of noncompliance with environmental laws. Any environmental violation or remediation requirement could also partially or completely shut down our research and manufacturing facilities and operations, which would have a material adverse effect on our business. The risk of accidental contamination or injury from these hazardous materials cannot

be completely eliminated and exposure of individuals to these materials could result in substantial fines, penalties or damages that are not covered by insurance.

Our total revenue could be affected by third-party reimbursement policies and potential cost constraints.

The end-users of our products are primarily physicians and other healthcare providers. In the U.S., healthcare providers such as hospitals and physicians who purchase diagnostic products generally rely on third-party payers, principally private health insurance plans, federal Medicare and state Medicaid, to reimburse all or part of the cost of the procedure. Use of our products would be adversely impacted if physicians and other healthcare providers do not receive adequate reimbursement for

the cost of our products by their patients' third-party payers. Our total revenue could also be adversely affected by changes or trends in reimbursement policies of these governmental or private healthcare payers. We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the U.S. in recent years, currently available levels of reimbursement may not continue to be available in the future for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the U.S. or foreign markets, current reimbursement amounts may be decreased in the future and future legislation, regulation or reimbursement policies of third-party payers may reduce the demand for our products or adversely impact our ability to sell our products on a profitable basis.

Unexpected increases in, or inability to meet, demand for our products could require us to spend considerable resources to meet the demand or harm our reputation and customer relationships if we are unable to meet demand.

Our inability to meet customer demand for our products, whether as a result of manufacturing problems or supply shortfalls, could harm our customer relationships and impair our reputation within the industry. In addition, our product manufacturing of certain product lines is concentrated in one or more of our manufacturing sites. Weather, natural disasters (including pandemics), fires, terrorism, political change, failure to follow specific internal protocols and procedures, equipment malfunction, environmental factors or damage to one or more of our facilities could adversely affect our ability to manufacture our products. This, in turn, could have a material adverse effect on our business.

If we experience unexpected increases in the demand for our products, we may be required to expend additional capital resources to meet these demands. These capital resources could involve the cost of new machinery or even the cost of new manufacturing facilities. This would increase our capital costs, which could adversely affect our earnings and cash resources. If we are unable to develop or obtain necessary manufacturing capabilities in a timely manner, our total revenue could be adversely affected. Failure to cost-effectively increase production volumes, if required, or lower than anticipated yields or production problems, including those encountered as a result of changes that we may make in our manufacturing processes to meet increased demand or changes in applicable laws and regulations, could result in shipment delays as well as increased manufacturing costs, which could also have a material adverse effect on our business, operating results and financial condition.

Unexpected increases in demand for our products could also require us to obtain additional raw materials in order to manufacture products to meet the demand. Some raw materials require significant ordering lead time and we may not be able to timely access sufficient raw materials in the event of an unexpected increase in demand, particularly those obtained from a sole supplier or a limited group of suppliers.

Interruptions in the supply of raw materials and other products and services could adversely affect our operations and financial results.

We depend on third-party manufacturers and suppliers for some of our products, or components and materials used in our products. Some of our raw materials, equipment and components are currently obtained from a sole supplier or a limited group of suppliers. We have long-term supply agreements with many of these suppliers, but these long-term agreements involve risks for us, such as our potential inability to obtain an adequate supply of quality raw materials, equipment or components and our reduced control over pricing, quality and timely delivery. It is also possible that one or more of these suppliers may become unwilling or unable to deliver materials or components to us. In addition, due to regulatory requirements relating to the qualification of suppliers, we may not be able to establish additional or replacement sources on a timely basis or without excessive cost. Any shortfall in our supply of raw materials, equipment or components, or our inability to quickly and cost-effectively obtain alternative sources for this supply, could have a material adverse effect on our business and operating results.

In addition, we use third party packaging companies to ship our products to customers. An interruption in the businesses of these third party packaging companies could result in a delay of shipments to customers.

If one or more of our products is claimed to be defective, we could be subject to claims of liability and harm to our reputation that could adversely affect our business.

A claim of a defect in the design or manufacture of our products could have a material adverse effect on our reputation in the industry and subject us to claims of liability for injuries and otherwise. Any substantial underinsured loss resulting from such a claim would have a material adverse effect on our operating results and financial conditions and the damage to our reputation or product lines in the industry could have a material adverse effect on our business.

We are exposed to business risk which, if not covered by insurance, could have an adverse effect on our results of operations.

We face a number of business risks, including exposure to product liability claims. Although we maintain insurance for a number of these risks, we may face claims for types of damages, or for amounts of damages, that are not covered by our insurance. For example, although we currently carry product liability insurance for liability losses, there is a risk that product liability or other claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy. Also, our existing insurance may not be renewed at the same cost and level of coverage as currently in effect, or may not be renewed at all. Further, we do not currently have insurance against many environmental risks we confront in our business. If we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, whether arising out of product liability matters, cybersecurity matters, or from some other matter, that claim could have a material adverse effect on our results of operations.

Failures in our information technology and storage systems could significantly disrupt our business or force us to expend excessive costs.

We utilize complex information technology systems to support our business and process, transmit, and store information, including sensitive personal information and proprietary or confidential information. In addition, some of our products include information technology that collects data regarding patients on behalf of our customers and some connect to our systems for maintenance purposes. We cannot be sure that our systems will meet our future business needs or that necessary upgrades will operate as designed, which could result in excessive costs or disruptions in portions of our business. In particular, any disruptions, delays or deficiencies caused by our enterprise resource planning system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business. In addition, despite the implementation of security measures, information technology systems are vulnerable to damage from a variety of sources, including computer viruses, unauthorized access, telecommunications or network failures, malicious human acts, terrorism and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, could result in a material disruption in our operations. Furthermore, to the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could face a variety of negative consequences, including regulatory actions or litigation, fines or penalties, adverse publicity, increased cybersecurity protection costs, and lost revenue.

Our business could be negatively affected by the loss of or the inability to hire key personnel.

Our future success depends in part on our ability to retain our key technical, sales, marketing and executive personnel and our ability to identify and hire additional qualified personnel. Competition for these personnel is intense, both in the industry in which we operate and where our operations are located. Further, we expect to grow our operations, and our needs for additional management and other key personnel are expected to increase. If we are not able to retain existing key personnel, or timely identify and hire replacement or additional qualified personnel to meet expected growth, our business could be adversely impacted. In addition, the loss of any of our key personnel, particularly key research and development personnel, could harm our business and prospects and could impede the achievement of our research and development, operation or strategic objectives.

We face risks relating to our international sales, including inherent economic, political and regulatory risks, which could impact our financial performance, cause interruptions in our current business operations and impede our growth strategy.

Our products are sold internationally, with the majority of our international sales to our customers in Europe and Asia-Pacific. We currently sell and market our products through distributor organizations and sales agents. Sales to foreign customers accounted for 17%, 14%, and 13% of our total revenue for the years ended December 31, 2016, 2015 and 2014, respectively. Our international sales are subject to inherent economic, political and regulatory risks, which could impact our financial performance, cause interruptions in our current business operations and impede our

international growth. These foreign risks include, among others:

- compliance with multiple different registration requirements and new and changing registration requirements, our inability to benefit from registration for our products inasmuch as registrations may be controlled by a distributor, and the difficulty in transitioning our product registrations;
- compliance with complex foreign and U.S. laws and regulations that apply to our international operations, including U.S. laws such as import/export limitations, the Foreign Corrupt Practices Act, and local laws

prohibiting corrupt payments to governmental officials, could expose us or our employees to fines and criminal sanctions and damage our reputation;

- tariffs or other barriers as we continue to expand into new countries and geographic regions;
- exposure to currency exchange fluctuations against the U.S. dollar;
- longer payment cycles, generally lower average selling prices and greater difficulty in accounts receivable collection;
- reduced, or lack of, protection for, and enforcement of, intellectual property rights;
- political and economic instability in some of the regions where we currently sell our products or that we may expand into in the future;
- complex and potentially adverse tax consequences; and
- diversion to the U.S. of our products sold into international markets at lower prices.

Currently, the majority of our international sales are negotiated for and paid in U.S. dollars. Nonetheless, these sales are subject to currency risks, since changes in the values of foreign currencies relative to the value of the U.S. dollar can render our products comparatively more expensive. These exchange rate fluctuations could negatively impact international sales of our products, as could changes in the general economic conditions in those markets. In order to maintain a competitive price for our products internationally, we may have to continue to provide discounts or otherwise effectively reduce our prices, resulting in a lower margin on products sold internationally. Continued change in the values of the Euro, the Japanese Yen and other foreign currencies could have a negative impact on our business, financial condition and results of operations.

In addition, we have certain supply agreements with foreign vendors whereby we share the foreign currency exchange fluctuation risk. We may, in the future, enter into similar arrangements.

Sales of our common stock in the public market could lower the market price for our common stock and adversely impact the trading price of our securities.

We may need to seek additional capital. If this additional financing is obtained through the issuance of equity securities, debt convertible into equity or options or warrants to acquire equity securities, our existing stockholders could experience significant dilution upon the issuance, conversion or exercise of such securities. In addition, a substantial number of shares of our common stock is reserved for issuance upon the conversion of our Convertible Senior Notes, exercise of stock options and vesting of other equity awards.

The issuance of additional shares of our common stock, or issuances of additional securities convertible into or exercisable for shares of our common stock or other equity linked securities, including, convertible debt, preferred stock or warrants, could dilute the ownership interest of our common stockholders and could depress the market price of shares of our common stock and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock.

We also have a number of institutional stockholders that own significant blocks of our common stock. If one or more of these stockholders were to sell large portions of their holdings in a relatively short time, for liquidity or other reasons, the prevailing market price of shares of our common stock could be negatively affected.

The price of our stock may fluctuate unpredictably in response to factors unrelated to our operating performance.

The stock market periodically experiences significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may cause the market price of our common stock to drop. In particular, the market price of securities of smaller medical device companies, like ours, has been very unpredictable and may vary in response to:

- announcements by us or our competitors concerning technological innovations;
- introductions of new products;
- FDA and foreign regulatory actions;
- developments or disputes relating to patents or proprietary rights;
- failure to meet the expectations of stock market analysts and investors;
- changes in stock market analyst recommendations regarding our common stock;
- changes in healthcare policy in the U.S. or other countries; and
- general stock market conditions and other factors unrelated to our operating performance.

23

Some provisions of our charter documents, Delaware law, and our Convertible Senior Notes may make takeover attempts difficult, which could depress the price of our stock and inhibit one's ability to receive a premium price for their shares.

Provisions of our amended and restated certificate of incorporation could make it more difficult for a third party to acquire control of our business, even if such change in control would be beneficial to our stockholders. Our amended and restated certificate of incorporation allows our board of directors to issue up to five million shares of preferred stock and to fix the rights and preferences of such shares without stockholder approval. Any such issuance could make it more difficult for a third party to acquire our business and may adversely affect the rights of our stockholders. Our amended and restated bylaws include advance notice requirements for stockholder proposals that require stockholders to give written notice of any proposal or director nomination to us within a specified period of time prior to any stockholder meeting and do not permit stockholders to call a special meeting of the stockholders, unless such stockholders hold not less than 50% of our stock entitled to vote at the meeting.

We are also subject to anti-takeover provisions under Delaware law. Together these provisions may delay, deter or prevent a change in control of us, adversely affecting the market price of our common stock.

In addition, the terms of our Convertible Senior Notes require us to offer to purchase the notes for cash in the event of a fundamental change. A non-stock takeover of our company may trigger the requirement that we purchase the Convertible Senior Notes. This feature may have the effect of delaying or preventing a takeover of our company that would otherwise be beneficial to investors.

We do not anticipate declaring any cash dividends on our common stock.

We have never declared or paid cash dividends on our common stock and do not plan to pay any cash dividends in the near future. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

At December 31, 2016, we occupied the indicated square footage in the leased facilities described below:

Location	Status	Lease term	Square Footage	Primary Use
San Diego, CA (McKellar)	Leased	2020 - options to extend for three additional 5 year periods	78,000	Administrative offices, research and development and manufacturing
San Diego, CA (High Bluff)	Leased	2022 - options to extend for two additional 5 year periods	30,000	Administrative offices, sales and marketing (principal executive offices)
Athens, OH	Leased	2022 - options to extend for one additional 5 year period	94,000	Administrative offices, sales and marketing, research and development and manufacturing
Beverly, MA	Leased	2020 - options to extend for two additional 5 year periods	9,700	Administrative offices, research and development and manufacturing

We believe that our facilities are adequate for our current needs, and we currently do not anticipate any material difficulty in renewing any of our leases as they expire or securing additional or replacement facilities, in each case, on commercially reasonable terms. However, in anticipation of our growth strategy, we may pursue alternative facilities.

Item 3. Legal Proceedings

We are involved in various claims and litigation matters from time to time in the ordinary course of business. We believe that all such current legal actions, in the aggregate, will not have a material adverse effect on the company. We also maintain insurance, including coverage for product liability claims, in amounts which we believe are appropriate given the nature of our business.

Item 4. Mine Safety Disclosures

Not applicable.

Part II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

COMMON STOCK PRICE RANGE

Our common stock is traded on the Nasdaq Global Market under the symbol “QDEL.” The following table sets forth the range of high and low sales prices for our common stock for the periods indicated.

Quarter Ended	Low	High
December 31, 2016	$20.88	$21.44
September 30, 2016	$20.96	$22.20
June 30, 2016	$17.20	$18.00
March 31, 2016	$16.98	$17.48
December 31, 2015	$21.07	$21.41
September 30, 2015	$18.56	$19.07
June 30, 2015	$22.75	$23.16
March 31, 2015	$26.66	$27.53

As of February 10, 2017, we had approximately 400 common stockholders of record. No cash dividends were declared for our common stock during the fiscal years ended in 2016 or 2015, and we do not anticipate paying any dividends in the foreseeable future.

Stock Repurchases

During the year ended December 31, 2016, we repurchased 1,152,386 shares of outstanding common stock under the Company's previously announced share repurchase program for approximately $19.6 million. Additionally, 29,095 shares of outstanding common stock with a value of $0.5 million were repurchased in connection with payment of minimum tax withholding obligations for certain employees relating to the lapse of restrictions on certain RSUs. These shares are not considered repurchases under the Company’s repurchase program. As of December 31, 2016, there was $35.0 million available under the Company's share repurchase program.

The table below sets forth information regarding repurchases of our common stock by us during the three months ended January 1, 2017:

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 (2)
October 3, 2016 - October 30, 2016	—		—	$35,006,981
October 31, 2016 - November 27, 2016	—		—	$35,006,981
November 28, 2015 - January 1, 2016	3,396	$21.35	—	$35,006,981
Total	3,396	$21.35	—	$35,006,981

(1) We repurchased 3,396 shares of common stock from employees in connection with payment of minimum tax withholding obligations related to the lapse of restrictions on certain RSUs during the three months ended December 31, 2016.

(2) On January 25, 2016, we announced that the Board of Directors authorized an amendment to the Company's previously announced stock repurchase program to (i) replenish the amount available for repurchase under the program back to the previously authorized repurchase amount of $50.0 million, (ii) approve the addition of

repurchases of the Company's Convertible Senior Notes under the program and (iii) extend the expiration date of the program to January 25, 2018. Under the amended program, the Company may repurchase, in the aggregate, up to $50.0 million in shares of its common stock and/or its Convertible Senior Notes. The amounts provided in this column give effect to the repurchase of our Convertible Senior Notes that are in addition to the repurchases of our common stock shown in this table.

STOCKHOLDER RETURN PERFORMANCE GRAPH

Set forth below is a line graph comparing the yearly percentage change in the cumulative total stockholder return on our common stock with the cumulative total return of the Nasdaq Composite Index, Nasdaq Health Care Index, and Nasdaq US Benchmark Medical Supplies Index for the period beginning December 31, 2011 and ending December 31, 2016. The graph assumes an initial investment of $100 on December 31, 2011 in our common stock, the Nasdaq Composite Index, the Nasdaq US Benchmark Medical Supplies Index, the Nasdaq Health Care Index and reinvestment of dividends. The stock price performance of our common stock depicted in the graph represents past performance only and is not necessarily indicative of future performance.

COMPARISON OF 5 YEAR TOTAL CUMULATIVE RETURN

Among Quidel Corporation, the NASDAQ Composite, NASDAQ US Benchmark Medical Supplies and NASDAQ Health Care Indices

	Base Period					
Company/Index	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015	12/31/2016
Quidel Corporation	$ 100.00	$ 123.40	$ 204.16	$ 191.14	$ 140.12	$ 141.57
NASDAQ Composite	$ 100.00	$ 115.91	$ 160.32	$ 181.80	$ 192.21	$ 206.63
NASDAQ US Benchmark Medical Supplies	$ 100.00	$ 121.40	$ 146.72	$ 174.19	$ 190.86	$ 215.74
NASDAQ Health Care	$ 100.00	$ 127.24	$ 199.82	$ 256.70	$ 274.30	$ 227.91

Item 6. Selected Financial Data

The following table presents selected consolidated financial data of Quidel Corporation. This historical data should be read in conjunction with the Consolidated Financial Statements and related Notes thereto in Item 8 and "Management's Discussion and Analysis of Financial Condition and Results of Operation" in Item 7 in this Annual Report.

Consolidated Statements of Operations

	Year ended December 31,				
	2016 (1)	2015	2014	2013 (1)	2012
	(in thousands, except per share data)				
Total revenues	$191,603	$196,129	$184,158	$177,325	$157,719
Costs and expenses					
Cost of sales (excludes amortization of intangible assets) (2)	73,414	71,688	74,180	66,976	61,285
Research and development	38,672	35,514	37,913	34,186	27,716
Sales and marketing	47,821	47,886	43,076	35,744	32,297
General and administrative	27,062	29,447	25,811	25,581	19,800
Amortization of intangible assets from acquired businesses and technology	9,073	8,856	8,828	8,171	6,935
Impairment loss	—	—	3,558	—	—
Facility restructuring charge	—	—	—	1,825	—
Total costs and expenses	196,042	193,391	193,366	172,483	148,033
Operating income (loss)	(4,439)	2,738	(9,208)	4,842	9,686
Interest expense, net	(11,760)	(12,035)	(1,775)	(1,408)	(2,075)
(Loss) income before (benefit) provision for taxes	(16,199)	(9,297)	(10,983)	3,434	7,611
(Benefit) provision for income taxes	(2,391)	(3,218)	(3,909)	(3,956)	2,618
Net (loss) income	$(13,808)	$(6,079)	$(7,074)	$7,390	$4,993
Basic earnings (loss) per share	$(0.42)	$(0.18)	$(0.21)	$0.22	$0.15
Diluted earnings (loss) per share	$(0.42)	$(0.18)	$(0.21)	$0.21	$0.15
Shares used in basic per share calculation	32,708	34,104	34,451	33,836	33,068
Shares used in diluted per share calculation	32,708	34,104	34,451	34,947	33,702

Balance Sheet Data

	December 31,				
	2016 (1)	2015	2014	2013 (1)	2012
	(in thousands)				
Cash and cash equivalents	$169,508	$191,471	$200,895	$8,388	$14,856
Working capital	$191,782	$209,834	$238,096	$54,610	$52,271
Total assets	$388,250	$406,505	$447,411	$271,485	$242,099
Long-term debt and lease obligation, net of current portion	$148,319	$147,329	$142,575	$5,126	$10,567
Stockholders' equity	$200,630	$218,676	$245,011	$223,779	$199,780
Common shares outstanding	32,897	33,323	34,433	34,073	33,451

(1) Includes the results of operations of BioHelix, AnDiaTec and Immutopics from dates of acquisition, May 6, 2013, August 26, 2013 and March 18, 2016, respectively.

(2) Excludes amortization of intangible assets of $6,458, $6,341, $6,283, $6,079 and $5,753 for the years ended December 31, 2016, 2015, 2014, 2013 and 2012, respectively.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations contains forward-looking statements within the meaning of the federal securities laws that involve material risks and uncertainties. This discussion should be read in conjunction with "A Warning About Forward-Looking Statements" on page 2 and "Risk Factors" under Item 1A of this Annual Report. In addition, our discussion of the financial condition and results of operations of Quidel Corporation in this Item 7 should be read in conjunction with our Consolidated Financial Statements and the related Notes included elsewhere in this Annual Report.

Overview and Executive Summary

We have a leadership position in the development, manufacturing and marketing of diagnostic testing solutions. These diagnostic testing solutions are separated into our four product categories, including: immunoassays, molecular assays, virology and specialty products. We sell our products directly to end users and distributors, in each case, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, leading universities, retail clinics, pharmacies and wellness screening centers. We market our products in the U.S. through a network of national and regional distributors and a direct sales force. Internationally, we sell primarily through distributor arrangements. For the year ended December 31, 2016, total revenue decreased 2% to $191.6 million as compared to the year ended December 31, 2015. A majority of our total revenues relate to three product families: Influenza, Strep A and pregnancy tests. For the years ended December 31, 2016, 2015 and 2014, we derived approximately 62%, 65% and 64%, respectively, of our total revenues from sales of our influenza, Group A Strep and pregnancy tests. Additionally, a significant portion of our total revenue is from a relatively small number of distributors. Approximately 44%, 48% and 48% of our total revenue for the years ended December 31, 2016, 2015 and 2014, respectively, were related to sales through our three largest distributors.

Our primary objective is to increase shareholder value by building a broader-based diagnostic company capable of delivering revenue growth and consistent operating results. Our strategy is to identify potential market segments that provide, or are expected to provide, significant total market opportunities, and in which we can be successful by applying our significant expertise and know-how to develop differentiated technologies and products.

Our diagnostic testing solutions are designed to provide specialized results that serve a broad range of customers, by addressing the market requirements of ease of use, reduced cost, increased test accuracy and reduced time to result. Our current approach to address this diagnostic continuum relative to our strategy is comprised of the following:

- rapid point-of-care immunoassay tests for use in physician offices, hospital laboratories and emergency departments, retail clinics, pharmacies and other urgent care or alternative site settings;
- direct fluorescent assays ("DFA") and culture-based tests for the clinical virology laboratory;
- molecular diagnostic tests across a number of laboratory and other segments; and
- specialty products serving the bone health, autoimmune and complement research communities.

Our current focus to accomplish our primary objective includes the following:

- leveraging our current infrastructure to develop and launch new rapid immunoassays such as additional assays for our FDA approved Sofia® and next generation analyzers;
- developing a molecular diagnostics franchise that incorporates three distinct testing platforms, AmpliVue®, Savanna™ and Solana® and that leverages our molecular assay development competencies; and
- strengthening our position with distribution partners and our end-user customers to gain more emphasis on our products in the U.S. and abroad.

Our current initiatives to execute this strategy include the following:

- continue to focus our research and development efforts on three areas:
- new proprietary product platform development;
- the creation of improved products and new products for existing markets and unmet clinical needs; and
- pursuit of collaborations with, or acquisitions of, other companies for new and existing products and markets that advance our differentiated strategy.

- provide clinicians with validated studies that encompass the clinical efficacy and economic efficiency of our diagnostic tests for the professional market;

- strengthen our market and brand leadership in infectious diseases, women's health and gastrointestinal diseases by acquiring and/or developing and introducing clinically superior diagnostic solutions;
- strengthen our direct sales force to enhance relationships with integrated delivery networks, laboratories and hospitals, with a goal of driving growth through improved physician and laboratorian satisfaction;
- leverage our wireless connectivity and data management systems, including cloud-based tools;
- support payer evaluation of diagnostic tests and establishment of favorable reimbursement rates;
- continue to create strong global alliances to support our efforts to achieve leadership in key markets and expand our presence in emerging markets; and
- further refine our manufacturing efficiencies and productivity improvements to improve profit, with continued focus on profitable products and markets and our efforts to leverage our competency in new product development.

Product development activities are inherently uncertain, and there can be no assurance that we will be able to obtain regulatory body clearance to market any of our products, or if we obtain clearances, that we will successfully commercialize any of our products. In addition, we may terminate our development efforts with respect to one or more of our products under development at any time, including before or during clinical trials.

Outlook

We anticipate revenue growth over the next year and a related positive impact on gross margin and earnings, assuming relatively normal respiratory seasons. This growth is expected to be driven primarily by increased sales of our Sofia assays and molecular products. In addition, we expect continued and significant investment in research and development activities as we invest in our second generation Sofia and molecular platforms. We will continue our focus on prudently managing our business and delivering solid financial results, while at the same time striving to continue to introduce new products to the market and maintaining our emphasis on research and development investments for longer term growth. Finally, we will continue to evaluate opportunities to acquire new product lines, technologies and companies.

Results of Operations

Comparison of years ended December 31, 2016 and 2015

Total Revenues

The following table compares total revenues for the years ended December 31, 2016 and 2015 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2016	2015	$	%
Immunoassays	$121,416	$130,348	$(8,932)	(7)%
Molecular	9,506	5,424	4,082	75 %
Virology	40,083	43,747	(3,664)	(8)%
Specialty products	11,211	9,001	2,210	25 %
Royalties, grants and other	9,387	7,609	1,778	23 %
Total revenues	$191,603	$196,129	$(4,526)	(2)%

For the year ended December 31, 2016, total revenues decreased 2% to $191.6 million. The decrease in total revenues was due to a decrease in immunoassay and virology product revenues due to a weaker Influenza season in the first quarter of 2016 compared to the previous year. This decrease was partially offset by growth in all of our molecular product lines. The acquisition of Immutopics, Inc. (Immutopics) contributed to the growth in our specialty products category. Royalties, grants and other revenue increased primarily due to timing of grant revenues associated with the amended Bill and Melinda Gates Foundation grant and our Savanna MDx development program.

Cost of Sales

Cost of sales increased to 38% of total revenues, for the year ended December 31, 2016 compared to 37% of total revenues, for the year ended December 31, 2015. The increase in cost of sales as a percentage of revenue was primarily driven by unfavorable product mix, with lower Influenza product sales in the same period as compared to the prior year.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2016 and 2015 (in thousands, except percentages):

	For the year ended December 31,					
	2016		2015			
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues	Increase (decrease) $	Increase (decrease) %
Research and development	$38,672	20 %	$35,514	18 %	$3,158	9 %
Sales and marketing	$47,821	25 %	$47,886	24 %	$(65)	— %
General and administrative	$27,062	14 %	$29,447	15 %	$(2,385)	(8)%
Amortization of intangible assets from acquired businesses and technology	$9,073	5 %	$8,856	5 %	$217	2 %

Research and Development Expense

Research and development expense for the year ended December 31, 2016 increased from $35.5 million to $38.7 million primarily due to an increase in development spending for the Savanna MDx platform and our next generation Sofia instrument, and an increase in clinical trials spending for our Solana and Sofia products. These increases are offset by lower spending on development of our Lyra products.

Research and development expenses include direct external costs such as fees paid to third-party contractors and consultants, and internal direct and indirect costs such as compensation and other expenses for research and development personnel, supplies and materials, clinical trials and studies, facility costs and depreciation.

Due to the risks inherent in the product development process and given the early-stage of development of certain projects, we are unable to estimate with meaningful certainty the costs we will incur in the continued development of our product candidates for commercialization. We expect our research and development costs to be substantial as we move other product candidates into preclinical and clinical trials and advance our existing product candidates into later stages of development.

Sales and Marketing Expense

Sales and marketing expense for the year ended December 31, 2016 decreased from $47.9 million to $47.8 million, remaining relatively flat over prior year. In 2014, we expanded our sales force and at December 31, 2016, we employed more than 100 U.S. sales representatives. We are utilizing this sales force to work closely with our key distributors to drive market penetration of our products in the U.S. POC market, with a particular focus on addressing acute care and integrated delivery network customers.

General and Administrative Expense

General and administrative expense for the year ended December 31, 2016 decreased from $29.4 million to $27.1 million. The decline was due primarily to business development expenditures in the prior year period that did not repeat during 2016, as well as the suspension of the medical device excise tax for 2016. These decreases were partially offset by increased integration costs associated with the acquisition of Immutopics.

Amortization of Intangible Assets from Acquired Businesses and Technology

Amortization of intangible assets from acquired businesses consists of customer relationships, purchased technology and patents and trademarks acquired in connection with our acquisitions of Diagnostic Hybrids, Inc., BioHelix, AnDiaTec and Immutopics. Amortization increased slightly in 2016 compared to the prior year primarily due to the additional amortization of intangible assets acquired with the Immutopics acquisition in March 2016.

Interest Expense, Net

Interest expense relates to accrued interest for the coupon and accretion of the discount on our $172.5 million 3.25% Convertible Senior Notes due 2020 ("Convertible Senior Notes") issued in December 2014 and interest paid on our lease obligation associated with our San Diego McKellar facility. The decrease in interest expense of $0.3 million for the year ended December 31, 2016 was primarily due to a gain on extinguishment of debt related to the repurchase of $5.2 million in principal of our Convertible Senior Notes during the first quarter of 2016.

Income Taxes

We recognized an income tax benefit of $2.4 million and $3.2 million for the years ended December 31, 2016 and 2015, respectively. The decrease in the income tax benefit in 2016 was primarily driven by the incremental increase in the valuation allowance for our federal deferred tax assets.

Comparison of years ended December 31, 2015 and 2014

Total Revenues

The following table compares total revenues for the years ended December 31, 2015 and 2014 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2015	2014	$	%
Immunoassays	$130,348	$118,715	$11,633	10 %
Molecular	5,424	3,418	2,006	59 %
Virology	43,747	44,771	(1,024)	(2)%
Specialty products	9,001	7,779	1,222	16 %
Royalties, grants and other	7,609	9,475	(1,866)	(20)%
Total revenues	$196,129	$184,158	$11,971	7 %

For the year ended December 31, 2015, total revenue increased 7% to $196.1 million from $184.2 million for the year ended December 31, 2014. The increase in total revenues was primarily due to an increase in sales of Influenza, Strep A and

31

RSV products in our immunoassay product category. Gains in the molecular category were driven by growth in our AmpliVue and Lyra products for detecting Herpes, Strep A and C. difficile. Specialty products revenue increased primarily due to growth in our Complement products. These increases were partially offset by a decrease in Virology driven by a decline in Herpes product revenues as customers transitioned to our new molecular platforms. Royalty, grants and other revenue also declined due to timing of grant revenues associated with the amended Bill and Melinda Gates Foundation grant agreement.

Cost of Sales

Cost of sales decreased to 37% of total revenues, for the year ended December 31, 2015 compared to 40% of total revenues, for the year ended December 31, 2014. The absolute dollar decrease in cost of sales of $2.5 million is primarily driven by the expiration of the amortization of the Alere settlement and improved manufacturing efficiencies. This was partially offset by the increased costs associated with greater revenues and increased depreciation expense on our instrument installed base.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2015 and 2014 (in thousands, except percentages):

	For the year ended December 31,								
	2015			2014					
	Operating expenses	As a % of total revenues		Operating expenses	As a % of total revenues		Increase (decrease) $	%	
Research and development	$35,514	18	%	$37,913	21	%	$(2,399)	(6	)%
Sales and marketing	$47,886	24	%	$43,076	23	%	$4,810	11	%
General and administrative	$29,447	15	%	$25,811	14	%	$3,636	14	%
Amortization of intangible assets from acquired businesses and technology	$8,856	5	%	$8,828	5	%	$28	—	%
Impairment loss	$—	—	%	$3,558	2	%	$(3,558)	N/A	
Facility restructuring charge	$—	—	%	$—	—	%	$—	N/A	

Research and Development Expense

Research and development expense for the year ended December 31, 2015 decreased from $37.9 million to $35.5 million primarily due to delayed timing of third-party developmental spend for the Savanna MDx platform partially offset by increased spend for our next generation Sofia instrument and development of related assays for Strep Pneumo, Vitamin D and Lyme disease.

Research and development expenses include direct external costs such as fees paid to consultants, and internal direct and indirect costs such as compensation and other expenses for research and development personnel, supplies and materials, clinical trials and studies, facility costs and depreciation.

Due to the risks inherent in the product development process and given the early-stage of development of certain projects, we are unable to estimate with meaningful certainty the costs we will incur in the continued development of our product candidates for commercialization. We expect our research and development costs to be substantial as we move other product candidates into preclinical and clinical trials and advance our existing product candidates into later stages of development.

Sales and Marketing Expense

Sales and marketing expense for the year ended December 31, 2015 increased from $43.1 million to $47.9 million driven primarily by increased headcount-related costs associated with the full year effect of a sales force expansion in 2014. At December 31, 2015, we employed more than 100 U.S. sales representatives. We utilized this expanded sales force to work closely with our key distributors to drive market penetration of our products in the U.S. POC market, with a particular focus on addressing acute care and integrated delivery network customers.

General and Administrative Expense

General and administrative expense for the year ended December 31, 2015 increased from $25.8 million to $29.4 million primarily due to an increase in one-time fees for professional services and internal costs related to business development activities. General and administrative expenses in 2015 and 2014 also included the 2.3% MDET.

Amortization of Intangible Assets from Acquired Businesses and Technology

Amortization of intangible assets from acquired businesses primarily consists of customer relationships, purchased technology and patents and trademarks acquired in connection with our acquisitions of DHI, BioHelix and AnDiaTec.

Impairment Loss

In 2014, we determined we would not be able to recover the carrying value of certain capitalized software, purchased in-process research and development and manufacturing line assets related to Project Stella (Bobcat). As a result, we recorded an impairment loss totaling $3.6 million in the third quarter of 2014. No such impairment occurred in 2015. See further discussion in Note 10 in the Notes to the Consolidated Financial Statements.

Interest Expense, Net

Interest expense primarily relates to accrued interest for the coupon and accretion of the discount on our $172.5 million 3.25% Convertible Senior Notes due 2020 ("Convertible Senior Notes") issued in December 2014 and interest paid on our lease obligation associated with our San Diego McKellar facility. The increase in interest expense of $10.3 million for the year ended December 31, 2015 was due to the interest expense related to the Convertible Senior Notes. There were no borrowings under our then existing senior secured syndicated credit facility (the “Senior Credit Facility”) during the years ended December 31, 2015 and 2014.

Income Taxes

We recognized an income tax benefit of $3.2 million and $3.9 million for the years ended December 31, 2015 and 2014, respectively. The decrease in the income tax benefit in 2015 was driven primarily by a lower pre-tax loss. Additionally, in 2014 we released tax reserves of approximately $1.0 million related to the expiration of the statute of limitations on assessment for certain state matters. We had no comparable release in 2015. Offsetting this impact, during 2014 the Company recorded a valuation allowance for deferred tax assets of $2.3 million, and an incremental $0.8 million in 2015 which increased the total valuation allowance to $3.1 million as of December 31, 2015.

Liquidity and Capital Resources

As of December 31, 2016 and 2015, our principal sources of liquidity consisted of the following (in thousands):

	December 31,	
	2016	2015
Cash and cash equivalents	$169,508	$191,471
Restricted cash	—	63
Cash, cash equivalents, and restricted cash	$169,508	$191,534
Working capital including cash, cash equivalents, and restricted cash	$191,782	$209,834
Amount available to borrow under the Senior Credit Facility	$—	$126,068

As of December 31, 2016, we had $169.5 million in cash and cash equivalents, a $22.0 million decrease from the prior year. During the year ended December 31, 2016, we repurchased an aggregate of $24.6 million in common stock and Convertible Senior Notes and used $5.1 million to acquire Immutopics. Our cash requirements fluctuate as a result of numerous factors, such as the extent to which we generate cash from operations, progress in research and development projects, competition and technological developments and the time and expenditures required to obtain governmental approval of our products. In addition, we intend to continue to evaluate candidates for new product lines, company or technology acquisitions or technology licensing. If we decide to proceed with any such transactions, we may need to incur additional debt or issue additional equity, to successfully complete the transactions.

Our primary source of liquidity, other than our holdings of cash and cash equivalents, has been cash flows from operations. Our ability to generate cash from operations provides us with the financial flexibility we need to meet operating, investing, and financing needs. We anticipate that our current cash and cash equivalents, together with cash provided by operating activities will be sufficient to fund our near term capital and operating needs for at least the next 12 months. Operating needs include the planned costs to operate our business, including amounts required to fund working capital and capital expenditures. Our primary short-term needs for capital, which are subject to change, include expenditures related to:

- support of commercialization efforts related to our current and future products, including support of our direct sales force and field support resources both in the United States and abroad;
- the continued advancement of research and development efforts;
- acquisitions of equipment and other fixed assets for use in our current and future manufacturing and research and development facilities;
- repurchases of our outstanding common stock or Convertible Senior Notes;
- potential strategic acquisitions and investments; and
- repayments of our lease obligation.

In December 2014, we issued Convertible Senior Notes in the aggregate principle amount of $172.5 million. The Convertible Senior Notes have a coupon rate of 3.25% and are due 2020. The Convertible Senior Notes were not convertible as of December 31, 2016. For detailed information of the terms of the Convertible Senior Notes, see Note 2 of the Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report under the heading “3.25% Convertible Senior Notes due 2020,” which is incorporated by reference herein.

On December 1, 2016, the Company voluntarily terminated its $140.0 million Senior Credit Facility. The facility was scheduled to mature on August 10, 2017. There were no outstanding borrowings at the time of termination and there was no borrowing or repayment activity under the facility during the years ended December 31, 2016, 2015 or 2014.

As of December 31, 2016, we have $5.2 million in fair value of contingent considerations associated with prior acquisitions to be settled in future periods.

In January 2016, our board of directors authorized an amendment to replenish the amount available under our share repurchase program up to an aggregate of $50.0 million in shares of common stock or Convertible Senior Notes. During 2016, we used $19.6 million to repurchase our common stock under the share repurchase program and $4.5 million to repurchase $5.2 million in principal amount of our outstanding Convertible Senior Notes.

We expect our revenue and operating expenses will significantly impact our cash management decisions. Our future capital requirements and the adequacy of our available funds will depend on many factors, including:

- our ability to successfully realize revenue growth from our new technologies and create innovative products in our markets;
- leveraging our operating expenses to realize operating profits as we grow revenue;
- competing technological and market developments; and
- the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product and service offerings.

Cash Flow Summary

	Year ended December 31,		
	2016	2015	2014
Net cash provided by operating activities	$11,815	$36,309	$35,686
Net cash used for investing activities	(16,970)	(17,032)	(11,241)
Net cash (used for) provided by financing activities	(16,799)	(28,684)	168,060
Effect of exchange rate changes on cash	(9)	(17)	2
Net (decrease) increase in cash and cash equivalents	$(21,963)	$(9,424)	$192,507

Cash provided by operating activities was $11.8 million during the year ended December 31, 2016. The major contributors to the use of cash during the year ended December 31, 2016 were a net loss of $13.8 million, a change in deferred tax assets and liabilities of $2.6 million and a net working capital use of $5.6 million. Offsetting this use of

cash was the add

back of non-cash items of $36.7 million associated with depreciation, amortization and stock-based compensation. The most significant change in operating assets and liabilities included an increase in accounts receivable of $6.3 million due to higher revenues in the fourth quarter of 2016 compared to prior year.

Cash provided by operating activities was $36.3 million during the year ended December 31, 2015. The Company had a net loss of $6.1 million, including non-cash charges of $23.4 million of depreciation and amortization of intangible assets and property and equipment, stock-based compensation of $7.4 million and amortization of debt discount and deferred issuance costs of $5.7 million. The most significant change in operating assets and liabilities included a decrease in accounts receivable of $16.1 million due to increased collection efforts and a $3.1 million decrease in restricted cash as grant terms were met under the Bill and Melinda Gates Foundation grant agreement. This was offset by a decrease of $3.1 million in payables as a result of decreased production in the fourth quarter of 2015 compared to the prior year.

Cash provided by operating activities was $35.7 million during the year ended December 31, 2014. The Company had a net loss of $7.1 million, including non-cash charges of $28.4 million of depreciation and amortization of intangible assets and property and equipment, impairment loss of $3.6 million and stock-based compensation of $6.7 million. The most significant change in operating assets and liabilities in 2014 included an increase in accounts receivable of $4.5 million related to an early start to a robust cold and flu season in the fourth quarter of 2014. This increase was favorably offset by extended payables terms, resulting in an increase of $4.4 million and reduced inventories of $2.9 million.

Our investing activities used $17.0 million during the year ended December 31, 2016; $5.1 million for the acquisition of Immutopics as more fully described in Note 11 in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report, and $11.9 million primarily for the acquisition of production equipment, Sofia instruments available for lease and building improvements. Our investing activities used $17.0 million during the year ended December 31, 2015 and $11.2 million during the year ended December 31, 2014 primarily related to the acquisition of production equipment, building improvements and Sofia instruments available for lease.

We are currently planning approximately $18.0 million in capital expenditures over the next 12 months. The primary purpose for our capital expenditures is to acquire manufacturing and scientific equipment, to purchase or develop information technology, and to implement facility improvements. We plan to fund these capital expenditures with the cash on our balance sheet. We have $6.6 million in firm purchase commitments with respect to such planned capital expenditures as of December 31, 2016.

Cash used by financing activities was $16.8 million during the year ended December 31, 2016, of which $20.2 million was used for repurchases of common stock primarily related to our share repurchase program, and $4.5 million was used for the repurchase of Convertible Senior Notes. These amounts were partially offset by proceeds from the issuance of common stock of $8.6 million. Cash used by financing activities was $28.7 million during the year ended December 31, 2015 and was driven primarily by $30.4 million of repurchases of common stock under our share repurchase program and $0.5 million of repurchases in connection with payment of minimum tax withholding obligations for certain employees relating to the lapse of restrictions on certain restricted stock units. Our financing activities provided $168.1 million of cash during the year ended December 31, 2014 primarily due to the issuance of the Convertible Senior Notes resulting in total proceeds of $172.5 million.

Off-Balance Sheet Arrangements

At December 31, 2016 and 2015, we did not have any relationships with unconsolidated entities or financial partners, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

Contractual Obligations

As of December 31, 2016, our future contractual obligations were as follows (in thousands):

	Payment due by period				
	Total	Less than 1 year	1-3 Years	3-5 Years	More than 5 years
Convertible Senior Notes (1)	$189,066	$5,438	$10,876	$172,752	$ —
Lease obligation (2)	3,806	937	1,902	967	—
Operating lease obligations (3)	12,134	2,245	4,638	4,626	625
Non-cancellable purchase commitments (4)	6,596	4,510	1,261	825	—
Total contractual obligations	$211,602	$13,130	$18,677	$179,170	$ 625

(1) Includes the principal amount of our Convertible Senior Notes due in December 2020, as well as interest payments to be made semi-annually.

(2) Reflects our lease obligation on the approximately 78,000 square-foot San Diego facility in place as of December 31, 2016. The facility is subject to a financing arrangement with payments through December 2020. Our future obligation under this financing arrangement is included in the table above.

(3) Reflects obligations on facilities and equipment under operating leases in place as of December 31, 2016. In October of 2013, we entered into a lease for approximately 30,000 square feet of office space in San Diego. The lease expires in 2022 with options to extend the lease for two additional five-year periods. In the fourth quarter of 2016, we exercised our renewal option for the Athens, Ohio location. The amended lease expires in 2022 with the option to extend the lease for one additional five-year period through 2027. Future minimum lease payments are included in the table above.

(4) Reflects our $6.6 million of non-cancellable commitments to purchase property and equipment, inventory and research and development services under contractual arrangements.

We have entered into various licensing agreements, which largely require payments based on specified product sales as well as the achievement of specific milestones. Royalty and license expenses under these various royalty and licensing agreements collectively totaled $0.8 million, $1.1 million and $8.9 million for the years ended December 31, 2016, 2015 and 2014, respectively, which included $0.7 million and $8.0 million in amortization expense for 2015 and 2014, respectively.

We exclude liabilities pertaining to uncertain tax positions from our table of contractual obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities, nor the amount of the final cash settlement. As of December 31, 2016, we had approximately $1.3 million of liabilities associated with uncertain tax positions. See Note 3 in the Notes to the Consolidated Financial Statements included in this Annual Report for further discussion of uncertain tax positions. The table also excludes $5.2 million in potential contingent consideration payments related to achievement of certain revenue targets under acquisition agreements. We have not included amounts in the table because we cannot make a reasonably reliable estimate regarding whether the milestones required for these payments will be achieved. See Note 6 in the Notes to the Consolidated Financial Statements included in this Annual Report for further discussion of our contingent consideration.

Recent Accounting Standards

For summary of recent accounting pronouncements applicable to our consolidated financial statements see “Company Operations and Summary of Significant Accounting Policies” in Note 1 to our Consolidated Financial Statements in Part II, Item 8, which is incorporated herein by reference.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. 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. On an on-going basis, we evaluate our estimates, including those related to customer programs and incentives, bad debts, inventories,

intangible assets, income taxes, stock-based compensation, restructuring and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that we believe are 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. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Revenue Recognition

The Company records revenues primarily from product sales. These revenues are recorded net of rebates and other discounts that are estimated at the time of sale, and are largely driven by various customer program offerings, including special pricing agreements, promotions and other volume-based incentives. Revenue from product sales are recorded upon passage of title and risk of loss to the customer. Change in title to the product and recognition of revenue occurs upon delivery to the customer when sales terms are free on board ("FOB") destination and at the time of shipment when the sales terms are FOB shipping point and there is no right of return.

A portion of product sales include revenues for diagnostic kits, which are utilized on leased instrument systems under the Company's "reagent rental" program. The reagent rental program provides customers the right to use the instruments at no separate cost to the customer in consideration for a multi-year agreement to purchase annual minimum amounts of consumables ("reagents" or "diagnostic kits"). When an instrument is placed with a customer under a reagent rental agreement, the Company retains title to the equipment and it remains capitalized on the Company's Consolidated Balance Sheet as property and equipment. The instrument is depreciated on a straight-line basis over the life of the instrument. Depreciation expense is recorded in cost of sales included in the Consolidated Statements of Operations. The reagent rental agreements represent one unit of accounting as the instrument and consumables (reagents) are interdependent in producing a diagnostic result and neither has a stand-alone value with respect to these agreements. No revenue is recognized at the time of instrument placement. All revenue is recognized when the title and risk of loss for the diagnostic kits have passed to the customer.

Royalty income from the grant of license rights is recognized during the period in which the revenue is earned and the amount is determinable from the licensee.

The Company earns income from grants for research and commercialization activities. On November 6, 2012, the Company was awarded a milestone-based grant totaling up to $8.3 million from the Bill and Melinda Gates Foundation to develop, manufacture and validate a quantitative, low-cost, nucleic acid assay for HIV drug treatment monitoring on the integrated Savanna MDx platform for use in limited resource settings. Upon execution of the grant agreement, the Company received $2.6 million to fund subsequent research and development activities and received milestone payments totaling $2.5 million in 2013. On September 10, 2014, the Company entered into an amended grant agreement with the Bill and Melinda Gates Foundation for additional funding of up to $12.6 million in order to accelerate the development of the Savanna MDx platform in the developing world. Upon execution of the amended grant agreement, the Company received $10.6 million in cash. The Company received payments of $2.4 million in April 2015 and $2.8 million in July 2016 based on milestone achievements for both the original and the amended grant agreements. Under the original and amended grant agreements, the Company recognizes grant revenue on the basis of the lesser of the amount recognized on a proportional performance basis or the amount of cash payments that are non-refundable as of the end of each reporting period. For the years ended December 31, 2016, 2015 and 2014, the Company recognized $6.5 million, $5.1 million and $6.3 million as grant revenue, respectively. Cash payments received were restricted as to use until expenditures contemplated in the grant were incurred or committed. As of December 31, 2016, all payment related milestones have been achieved and all of the grant revenue of $20.9 million has been recorded.

Stock-Based Compensation

Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option. The total number of stock options expected to vest is adjusted by estimated forfeiture rates. We determine the estimated fair value of each stock option on the date of grant using the Black-Scholes option valuation model. The computation of the expected option life is based on a weighted-average calculation combining the average life of options that have already been exercised and post-vest cancellations with the estimated life of the remaining vested and unexercised options. The expected volatility is based on the historical volatility of our stock. The risk-free interest rate is based on the U.S Treasury yield curve over the expected term of the option. Historically, we have not paid any cash dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future. Consequently, we use an expected dividend yield of zero in the Black-Scholes option valuation model. The

estimated forfeiture rate is based on our historical experience and future expectations.

Compensation expense for time-based restricted units are measured at the grant date and recognized ratably over the vesting period. We determine the fair value of time-based and performance-based restricted stock based on the closing market price of our common stock on the grant date. A portion of the restricted stock granted in 2012 and 2011 was performance-based

and vesting was tied to achievement of specific Company goals in 2014 and 2013, respectively. For purposes of measuring compensation expense, the amount of shares ultimately expected to vest is estimated at each reporting date based on management's expectations regarding the relevant performance criteria. The recognition of compensation expense associated with performance-based restricted stock requires judgment in assessing the probability of meeting the performance goals, as well as defined criteria for assessing achievement of the performance-related goals. The grant date of the performance-based restricted stock takes place when the grant is authorized and the specific achievement goals are communicated. The communication date of the performance goals can impact the valuation and associated expense of the restricted stock.

Reserve for Uncollectible Accounts Receivable

We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. Our allowance for doubtful accounts is based on our assessment of the collectability of specific customer accounts, the aging of accounts receivable, our history of bad debts, and the general condition of the industry. If a major customer's credit worthiness deteriorates, or our customers' actual defaults exceed our historical experience, our estimates could change and adversely impact our reported results.

Inventory

Our policy is to value inventories at the lower of cost or net realizable value. This policy requires us to make estimates regarding the market value of our inventories and the costs of completion, disposal or transportation. We determine excess and obsolete inventories based on an estimate of the future demand for our products within a specified time horizon, generally 12 months. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our revenue forecasts. If our actual demand is less than our forecast demand, we may be required to take additional excess inventory charges, which would decrease gross margin and adversely impact net operating results in the future.

Goodwill and Intangible Assets

The effective life and related amortization of intangible assets with definite lives will be based on the higher of the percentage of usage or the straight-line method. Useful lives are based on the expected number of years the asset will generate revenue or otherwise be used by us. Goodwill and in-process research and development that have indefinite lives are not amortized but instead are tested at least annually for impairment, or more frequently when events or changes in circumstances indicate that the asset might be impaired. Examples of such events or circumstances include:

- the asset's ability to continue to generate income from operations and positive cash flow in future periods;
- any volatility or significant decline in our stock price and market capitalization compared to our net book value;
- loss of legal ownership or title to an asset;
- significant changes in our strategic business objectives and utilization of our assets; and
- the impact of significant negative industry or economic trends.

If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

For goodwill and in-process research and development, a two-step test is used to identify the potential impairment and to measure the amount of impairment, if any. The first step is to compare the fair value of a reporting unit with the carrying amount, including goodwill and in-process research and development. If the fair value of a reporting unit exceeds its carrying amount, goodwill and in-process research and development are considered not impaired; otherwise, goodwill and in-process research and development are impaired and the loss is measured by performing step two. Under step two, the impairment loss is measured by comparing the implied fair value of the reporting unit with the carrying amount of goodwill and in-process research and development. We are required to perform periodic evaluations for impairment of goodwill balances. We completed our annual evaluation for impairment of goodwill and in-process research and development as of December 31, 2016 and determined that no impairment existed.

Determining the initial fair values and useful lives of the intangible assets acquired in connection with the Alere Amendment described in Note 6 in the Notes to Consolidated Financial Statements included in this Annual Report required the exercise of judgment. While there are a number of different generally accepted valuation methods to estimate the value of intangible assets, we used the discounted cash flow method in determining the value of licensed technology associated with the Alere Amendment. This method required significant management judgment to forecast

the future operating results used in the analysis. In addition, other significant estimates were required such as residual growth rates and discount factors. The estimates

we used to value and amortize intangible assets were consistent with the plans and estimates that we use to manage our business and were based on available historical information and industry estimates and averages. These judgments can significantly affect our net operating results.

Business Combinations

The cost of an acquired business is assigned to the tangible and identifiable intangible assets acquired and liabilities assumed on the basis of the estimated fair values at the date of acquisition. We assess fair value, which is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, using a variety of methods including, but not limited to, an income approach and a market approach such as the estimation of future cash flows of acquired business and current selling prices of similar assets. Fair value of the assets acquired and liabilities assumed, including intangible assets, in-process research and development (IPR&D), and contingent payments, are measured based on the assumptions and estimations with regards to the variable factors such as the amount and timing of future cash flows for the asset or liability being measured, appropriate risk-adjusted discount rates, nonperformance risk, or other factors that market participants would consider. Upon acquisition, we determine the estimated economic lives of the acquired intangible assets for amortization purposes, which are based on the underlying expected cash flows of such assets. When applicable, adjustments to inventory and property, plant and equipment are based on the fair market value of inventory and amortized into income based on the period in which the underlying inventory is sold. Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination that is not individually identified and separately recognized. Actual results may vary from projected results and assumptions used in the fair value assessments.

Software Development Costs

Software development costs associated with software to be sold, leased or otherwise marketed are expensed as incurred until technological feasibility has been established. After technological feasibility is established, software development costs are capitalized. The capitalized cost is amortized on a straight-line basis over the estimated product life or on the ratio of current revenues to total projected product revenues, whichever is greater.

Income Taxes

Significant judgment is required in determining our provision for income taxes, current tax assets and liabilities, deferred tax assets and liabilities, and our future taxable income, both as a whole and in various tax jurisdictions, for purposes of assessing our ability to realize future benefit from our deferred tax assets. A valuation allowance may be established to reduce our deferred tax assets to the amount that is considered more likely than not to be realized through the generation of future taxable income and other tax planning opportunities. In 2015 and 2016, we evaluated our gross deferred tax assets, including an assessment of cumulative income or loss over the prior three-year period and future periods, to determine if a valuation allowance was required. A significant piece of objective negative evidence evaluated was the cumulative before-tax loss incurred over the three-year periods ended December 31, 2016 and 2015. Such objective evidence limits the ability to consider other subjective evidence such as our projections for future profitability. On the basis of this evaluation, as of December 31, 2016, we recorded a valuation allowance of $7.8 million. This valuation allowance represents the portion of the deferred tax asset that management could no longer conclude was more likely or not to be realized. We will continue to assess the need for a valuation allowance on our deferred tax assets by evaluating both positive and negative evidence that may exist.

We recognize liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained during an audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While we believe that we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcome of examinations by tax authorities in determining the adequacy of our provision for income taxes. See Note 3 in the Notes to the Consolidated Financial Statements included in this Annual Report for more information on income taxes.

We recognize excess tax benefits associated with the exercise of stock options directly to stockholders' equity only when realized. Accordingly, deferred tax assets are not recognized for net operating loss and tax credit carryforwards

resulting from excess tax benefits. As of December 31, 2016 and 2015, deferred tax assets do not include $1.8 million and $1.3 million, respectively, of these excess tax benefits from employee stock option exercises that are a component of our net operating loss and tax credit carryforwards. As discussed in Note 1 in the Notes to the Consolidated Financial Statements in March 2016, the FASB issued guidance codified in ASU 2016-09 (Topic 718), Improvements to Employee Share Based Payments Accounting. Under the guidance, entities will no longer record excess tax benefits and certain tax deficiencies in additional paid-in capital (APIC). Instead, they will record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income

statement, and APIC pools will be eliminated. In addition, entities will recognize excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. The Company has excess tax benefits for which a benefit could not be previously recognized of approximately $1.8 million. Upon adoption the balance of the unrecognized excess tax benefits will be reversed with the impact recorded to (accumulated deficit) retained earnings, including any change to the valuation allowance as a result of the adoption. Due to the full valuation allowance on the U.S. deferred tax assets as of December 31, 2016, the Company does not expect any impact to the financial statements as a result of this adoption in the first quarter of 2017.

Convertible Debt

We account for convertible debt instruments that may be settled in cash upon conversion (including combination settlement of cash equal to the “principal portion” and delivery of the “share amount” in excess of the conversion value over the principal portion in shares of common stock and/or cash) by separating the liability and equity components of the instruments in a manner that reflects our nonconvertible debt borrowing rate. We determine the carrying amount of the liability component by measuring the fair value of similar debt instruments that do not have the conversion feature. If no similar debt instrument exists, we estimate fair value by using assumptions that market participants would use in pricing a debt instrument, including market interest rates, credit standing, yield curves and volatilities. Determining the fair value of the debt component requires the use of accounting estimates and assumptions. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense.

In December 2014, we issued $172.5 million aggregate principal amount of 3.25% Convertible Senior Notes due 2020. We assigned a value to the debt component of our Convertible Senior Notes equal to the estimated fair value of similar debt instruments without the conversion feature, which resulted in us recording the debt at a discount. We are amortizing the debt discount over the life of the Convertible Senior Notes as additional non-cash interest expense utilizing the effective interest method. For additional information, see Note 2 in the Notes to the Consolidated Financial Statements included in this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We are not subject to interest rate risk on our Convertible Senior Notes as the Notes have a fixed rate of 3.25%. For fixed rate debt, changes in interest rates will generally affect the fair value of the debt instrument, but not our earnings or cash flows. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to changes in interest rates.

Our current investment policy with respect to our cash and cash equivalents focuses on maintaining acceptable levels of interest rate risk and liquidity. Although we continually evaluate our placement of investments, as of December 31, 2016, our cash and cash equivalents were placed in funds held in government money market accounts and commercial paper.

Foreign Currency Exchange Risk

The majority of our international sales are negotiated for and paid in U.S. dollars. Nonetheless, these sales are subject to currency risks, since changes in the values of foreign currencies relative to the value of the U.S. dollar can render our products comparatively more expensive. These exchange rate fluctuations could negatively impact international sales of our products, as could changes in the general economic conditions in those markets. Continued change in the values of the Euro, the Japanese Yen and other foreign currencies could have an impact on our business, financial condition and results of operations. We do not currently hedge against exchange rate fluctuations, which means that we are fully exposed to exchange rate changes. In addition, we have certain agreements whereby we share the foreign currency exchange fluctuation risk. We may, in the future, enter into similar such arrangements.

Item 8. Financial Statements and Supplementary Data
Index of Consolidated Financial Statements and Schedule

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and
Stockholders of Quidel Corporation

We have audited the accompanying consolidated balance sheets of Quidel Corporation as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016. Our audits also included the financial statement schedule listed in the Index at Item 15(a)(2). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Quidel Corporation at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Quidel Corporation's internal control over financial reporting as of December 31, 2016, 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 16, 2017 expressed an unqualified opinion thereon.

s/ ERNST & YOUNG LLP

San Diego, California
February 16, 2017

QUIDEL CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands, except par value)

	December 31,	
	2016	2015
ASSETS		
Current assets:		
Cash and cash equivalents	$169,508	$191,471
Accounts receivable, net	24,990	18,398
Inventories	26,045	26,388
Restricted cash	—	63
Prepaid expenses and other current assets	4,851	4,344
Total current assets	225,394	240,664
Property, plant and equipment, net	50,858	52,547
Goodwill	83,834	80,730
Intangible assets, net	27,639	31,833
Other non-current assets	525	731
Total assets	$388,250	$406,505
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$16,047	$8,675
Accrued payroll and related expenses	9,642	9,627
Current portion of lease obligation	98	585
Current portion of contingent consideration	2,826	1,286
Deferred grant revenue	—	3,658
Other current liabilities	4,999	6,999
Total current liabilities	33,612	30,830
Long-term debt	144,340	143,297
Lease obligation, net of current portion	3,979	4,032
Contingent consideration—non-current	2,349	4,230
Deferred tax liability—non-current	58	1,970
Income taxes payable	1,045	910
Deferred rent	1,965	2,296
Other non-current liabilities	272	264
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $.001 par value per share; 5,000 shares authorized; none issued or outstanding at December 31, 2016 and 2015	—	—
Common stock, $.001 par value per share; 97,500 shares authorized; 32,897 and 33,323 shares issued and outstanding at December 31, 2016 and 2015, respectively	33	33
Additional paid-in capital	204,905	209,121
Accumulated other comprehensive loss	(53)	(31)
(Accumulated deficit) retained earnings	(4,255)	9,553
Total stockholders' equity	200,630	218,676
Total liabilities and stockholders' equity	$388,250	$406,505

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year ended December 31,		
	2016	2015	2014
Total revenues	$191,603	$196,129	$184,158
Costs and expenses			
Cost of sales (excludes amortization of intangible assets of $6,458, $6,341, and $6,283, respectively)	73,414	71,688	74,180
Research and development	38,672	35,514	37,913
Sales and marketing	47,821	47,886	43,076
General and administrative	27,062	29,447	25,811
Amortization of intangible assets from acquired businesses and technology	9,073	8,856	8,828
Impairment loss	—	—	3,558
Total costs and expenses	196,042	193,391	193,366
Operating (loss) income	(4,439)	2,738	(9,208)
Interest expense, net	(11,760)	(12,035)	(1,775)
Loss before benefit for income taxes	(16,199)	(9,297)	(10,983)
Benefit for income taxes	(2,391)	(3,218)	(3,909)
Net loss	$(13,808)	$(6,079)	$(7,074)
Basic and diluted loss per share	$(0.42)	$(0.18)	$(0.21)
Shares used in basic and diluted per share calculation	32,708	34,104	34,451

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year ended December 31,		
	2016	2015	2014
Net loss	$(13,808)	$(6,079)	$(7,074)
Other comprehensive loss, net of tax			
Changes in cumulative translation adjustment	(22)	(2)	(47)
Comprehensive loss	$(13,830)	$(6,081)	$(7,121)

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock					
	Shares	Par	Additional paid-in capital	Accumulated other comprehensive income (loss)	Retained earnings (accumulated deficit)	Total stockholders' equity
Balance at January 1, 2014	34,073	$34	$201,021	$ 18	$ 22,706	$223,779
Issuance of common stock under equity compensation plans	428	—	5,471	—	—	5,471
Convertible senior notes, equity portion, net of tax and issuance costs	—	—	29,758	—	—	29,758
Tax impact from the issuance of convertible senior notes	—	—	(11,362)	—	—	(11,362)
Stock-based compensation expense	—	—	6,442	—	—	6,442
Repurchases of common stock	(68)	—	(1,956)	—	—	(1,956)
Changes in cumulative translation adjustment, net of tax	—	—	—	(47)	—	(47)
Net loss	—	—	—	—	(7,074)	(7,074)
Balance at December 31, 2014	34,433	34	229,374	(29)	15,632	245,011
Issuance of common stock under equity compensation plans	308	—	3,318	—	—	3,318
Excess tax benefit from share-based compensation	—	—	571	—	—	571
Stock-based compensation expense	—	—	6,791	—	—	6,791
Repurchases of common stock	(1,418)	(1)	(30,933)	—	—	(30,934)
Changes in cumulative translation adjustment, net of tax	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	(6,079)	(6,079)
Balance at December 31, 2015	33,323	33	209,121	(31)	9,553	218,676
Issuance of common stock under equity compensation plans	755	—	9,365	—	—	9,365
Stock-based compensation expense	—	—	7,134	—	—	7,134
Repurchase of Convertible Senior Notes	—	—	(547)	—	—	(547)
Repurchases of common stock	(1,181)	—	(20,168)	—	—	(20,168)
Changes in cumulative translation adjustment, net of tax	—	—	—	(22)	—	(22)
Net loss	—	—	—	—	(13,808)	(13,808)
Balance at December 31, 2016	32,897	$33	$204,905	$ (53)	$ (4,255)	$200,630

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year ended December 31,		
	2016	2015	2014
OPERATING ACTIVITIES			
Net loss	$(13,808)	$(6,079)	$(7,074)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation, amortization and other	22,796	23,386	28,365
Stock-based compensation expense	7,986	7,419	6,724
Impairment loss	—	—	3,558
Amortization of debt discount and deferred issuance costs	5,891	5,664	629
Change in fair value of acquisition contingencies	(485)	(88)	(910)
Change in deferred tax assets and liabilities	(2,603)	(4,027)	(2,744)
Gain on extinguishment of Convertible Senior Notes	(421)	—	—
Excess tax benefit from share-based compensation	—	(571)	—
Changes in assets and liabilities:			
Accounts receivable	(6,265)	16,060	(4,547)
Inventories	859	(1,637)	2,862
Prepaid expenses and other current and non-current assets	(552)	(1,039)	787
Restricted cash	63	3,064	(2,158)
Accounts payable	4,323	(3,082)	4,380
Accrued payroll and related expenses	(375)	1,061	1,247
Income taxes payable	48	(64)	(1,036)
Deferred grant revenue	(3,658)	(2,672)	4,301
Other current and non-current liabilities	(1,984)	(1,086)	1,302
Net cash provided by operating activities	11,815	36,309	35,686
INVESTING ACTIVITIES			
Acquisitions of property, equipment and intangibles	(11,909)	(17,032)	(11,241)
Acquisition of Immutopics, net of cash acquired	(5,061)	—	—
Net cash used for investing activities	(16,970)	(17,032)	(11,241)
FINANCING ACTIVITIES			
Proceeds from issuance of Convertible Senior Notes	—	—	172,500
Proceeds from issuance of common stock	8,575	2,911	4,781
Payments of debt issuance costs	—	(365)	(4,712)
Excess tax benefit from share-based compensation	—	571	—
Payments on lease obligation	(540)	(509)	(441)
Repurchases of common stock	(20,168)	(30,934)	(1,956)
Repurchases of Convertible Senior Notes	(4,459)	—	—
Payments on acquisition contingencies	(207)	(129)	(2,112)
Payment for acquisition holdback	—	(229)	—
Net cash (used for) provided by financing activities	(16,799)	(28,684)	168,060
Effect of exchange rate changes on cash	(9)	(17)	2
Net (decrease) increase in cash and cash equivalents	(21,963)	(9,424)	192,507
Cash and cash equivalents, beginning of period	191,471	200,895	8,388
Cash and cash equivalents, at end of period	$169,508	$191,471	$200,895

See accompanying notes.

	Year ended December 31,		
	2016	2015	2014
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid during the period for interest	$6,488	$6,998	$981
Cash paid during the period for income taxes	$490	$1,922	$327
NON-CASH INVESTING ACTIVITIES			
Purchase of property, equipment and intangibles by incurring current liabilities	$3,280	$239	$900
NON-CASH FINANCING ACTIVITIES			
Decrease of accrued payroll and related expenses upon issuance of common stock	$539	$408	$663
Receivable for stock option exercises	$251	$—	$—
Debt issuance costs by incurring current liabilities	$—	$—	$365

See accompanying notes.

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Note 1. Company Operations and Summary of Significant Accounting Policies
Quidel Corporation (the "Company") commenced operations in 1979. The Company operates in one business segment, which develops, manufactures and markets rapid diagnostic testing solutions. These diagnostic tests can be categorized in the following areas: immunoassay, molecular, virology and specialty products. The Company sells its products directly to end users and distributors, in each case, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, leading universities, retail clinics and wellness screening centers. The Company markets its products in the U.S. through a network of national and regional distributors, and a direct sales force. Internationally, the Company sells and markets through distributor arrangements.
The accompanying consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with generally accepted accounting principles in the U.S.
Consolidation—The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.
Cash and Cash Equivalents—The Company considers cash equivalents to be highly liquid investments with a maturity at the date of purchase of three months or less. The Company invests its cash equivalents primarily in money market funds and commercial paper. Cash equivalents are maintained with high quality institutions.
Accounts Receivable—The Company sells its products directly to hospitals and reference laboratories in the U.S. as well as to distributors in the U.S. and internationally (see Note 7). The Company periodically assesses the financial strength of these customers and establishes reserves for anticipated losses when necessary, which historically have not been material. The Company's reserves primarily consist of amounts related to cash discounts and contract rebates. The balance of accounts receivable is net of reserves of $7.2 million and $7.5 million at December 31, 2016 and 2015, respectively.
Concentration of Credit Risk—Financial instruments that potentially subject the Company to significant concentrations of credit risk consists principally of trade accounts receivable.
The Company performs credit evaluations of its customers' financial condition and limits the amount of credit extended when deemed necessary, but generally requires no collateral. Credit quality is monitored regularly by reviewing credit history. The Company believes that the concentration of credit risk in its trade accounts receivables is moderated by its credit evaluation process, relatively short collection terms, the high level of credit worthiness of its customers, and letters of credit issued on the Company's behalf. Potential credit losses are limited to the gross value of accounts receivable.
Inventories—Inventories are stated at the lower of cost (first-in, first-out) or net realizable value. The Company reviews the components of its inventory on a quarterly basis for excess, obsolete and impaired inventory and makes appropriate dispositions as obsolete stock is identified. Inventories consisted of the following, net of reserves of $0.7 million at December 31, 2016 and 2015 (in thousands):

	December 31,	
	2016	2015
Raw materials	$9,297	$10,289
Work-in-process (materials, labor and overhead)	7,990	7,441
Finished goods (materials, labor and overhead)	8,758	8,658
Total inventories	$26,045	$26,388

Property, Plant and Equipment—Property, plant and equipment is recorded at cost and depreciated over the estimated useful lives of the assets (three to 15 years) using the straight-line method. Amortization of leasehold improvements is computed on the straight-line method over the estimated useful lives of the assets. The total expense for depreciation of fixed assets and amortization of leasehold improvements was $13.4 million, $12.7 million and $10.3 million for the years ended December 31, 2016, 2015 and 2014, respectively. Maintenance and minor repairs are charged to operations as incurred.

49

Property, plant and equipment consisted of the following (in thousands):

	December 31,	
	2016	2015
Equipment, furniture and fixtures	$61,972	$59,736
Building and improvements	34,243	33,048
Leased instruments	24,014	18,280
Land	1,080	1,080
Total property, plant and equipment, gross	121,309	112,144
Less: accumulated depreciation and amortization	(70,451)	(59,597)
Total property, plant and equipment, net	$50,858	$52,547

Goodwill and Intangible Assets—Intangible assets are recorded at cost and amortized on a straight-line basis over their estimated useful lives, except for software development costs and indefinite-lived intangibles such as goodwill. Software development costs associated with software to be sold, leased or otherwise marketed are expensed as incurred until technological feasibility has been established. After technological feasibility is established, software development costs are capitalized. The capitalized cost is amortized on a straight-line basis over the estimated product life or on the ratio of current revenues to total projected product revenues, whichever is greater. Amortization expense related to the capitalized software costs was $0.5 million, $0.6 million and $0.6 million for the years ended December 31, 2016, 2015 and 2014, respectively. The Company had goodwill of $83.8 million as of December 31, 2016 and $80.7 million as of December 31, 2015. Intangible assets consisted of the following (dollar amounts in thousands):

		December 31, 2016			December 31, 2015		
Description	Weighted-average useful life (years)	Gross assets	Accumulated amortization	Net	Gross assets	Accumulated amortization	Net
Purchased technology	8.4	53,600	(41,369)	12,231	52,560	(34,911)	17,649
Customer relationships	7.6	7,157	(5,928)	1,229	7,171	(4,972)	2,199
License agreements	10.4	6,009	(3,222)	2,787	5,512	(2,542)	2,970
Patent and trademark costs	12.0	11,240	(3,522)	7,718	10,530	(2,588)	7,942
Software development costs	5	6,000	(2,326)	3,674	2,913	(1,840)	1,073
Total intangible assets		$84,006	$ (56,367)	$27,639	$78,686	$ (46,853)	$31,833

Amortization expense was $9.5 million, $10.2 million and $17.4 million for the years ended December 31, 2016, 2015 and 2014, respectively. Included in this amortization expense amount for 2015 and 2014 is $0.7 million, and $8.0 million, respectively, of amortization for licensed technology recorded in cost of sales. This amount is related to the purchase of a license pursuant to the Alere Amendment as discussed in Note 6. The intangible asset associated with this intangible was fully amortized in the first quarter of 2015.

The expected future annual amortization expense of the Company’s intangible assets is as follows (in thousands):

For the years ending December 31,	Amortization expense
2017	$ 9,822
2018	4,332
2019	3,079
2020	2,700
2021	2,582
Thereafter	5,124
Total	$ 27,639

The Company recorded a $1.6 million impairment loss related to a discontinued research and development named Project Stella (Bobcat) during the third quarter of 2014. See further discussion in Note 10. The Company completed its annual evaluation for impairment of goodwill and determined that no impairment of goodwill existed as of December 31, 2016.

Impairment of Long-Lived Assets—The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the total book value of an asset may not be recoverable. An impairment loss is recognized when estimated undiscounted future cash flows expected to result from the use of the asset and the eventual disposition are less than its carrying amount. An impairment loss is equal to the excess of the book value of an asset over its determined fair value. For the year ended December 31, 2014, the Company recorded a $1.5 million impairment loss on software development costs related to Project Stella. See further discussion in Note 10. The Company recorded no impairment losses for the years ended December 31, 2016 and 2015.

Other current liabilities—Other current liabilities consisted of the following (in thousands):

	December 31,	
	2016	2015
Customer incentives	$3,766	$4,030
Accrued interest	227	202
Other	1,006	2,767
Total other current liabilities	$4,999	$6,999

Convertible Debt—The Company accounts for convertible debt instruments that may be settled in cash upon conversion (including combination settlement of cash equal to the “principal portion” and delivery of the “share amount” in excess of the conversion value over the principal portion in shares of common stock and/or cash) by separating the liability and equity components of the instruments in a manner that reflects our nonconvertible debt borrowing rate. The Company determines the carrying amount of the liability component by measuring the fair value of similar debt instruments that do not have the conversion feature. If no similar debt instrument exists, the Company estimates fair value by using assumptions that market participants would use in pricing a debt instrument, including market interest rates, credit standing, yield curves and volatilities. Determining the fair value of the debt component requires the use of accounting estimates and assumptions. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense. See Note 2 for additional discussion of the Convertible Senior Notes issued in December 2014.

Revenue Recognition—The Company records revenues primarily from product sales. These revenues are recorded net of rebates and other discounts that are estimated at the time of sale, and are largely driven by various customer program offerings, including special pricing agreements, promotions and other volume-based incentives. Revenue from product sales are recorded upon passage of title and risk of loss to the customer. Passage of title to the product and recognition of revenue occurs upon delivery to the customer when sales terms are free on board (“FOB”) destination and at the time of shipment when the sales terms are FOB shipping point and there is no right of return.

A portion of product sales includes revenues for diagnostic kits, which are utilized on leased instrument systems under the Company’s “reagent rental” program. The reagent rental program provides customers the right to use the instruments at no separate cost to the customer in consideration for a multi-year agreement to purchase annual minimum amounts of consumables (“reagents” or “diagnostic kits”). When an instrument is placed with a customer under a reagent rental agreement, the Company retains title to the equipment and it remains capitalized on the Company’s Consolidated Balance Sheets as property and equipment. The instrument is depreciated on a straight-line basis over the life of the instrument. Depreciation expense is recorded in cost of sales included in the Consolidated Statements of Operations. The reagent rental agreements represent one unit of accounting as the instrument and consumables (reagents) are interdependent in producing a diagnostic result and neither has a stand-alone value with respect to these agreements. No revenue is recognized at the time of instrument placement. All revenue is recognized when the title and risk of loss for the diagnostic kits have passed to the customer.

Royalty income from the grant of license rights is recognized during the period in which the revenue is earned and the amount is determinable from the licensee.

The Company earns income from grants for research and commercialization activities. On November 6, 2012, the Company was awarded a milestone-based grant totaling up to $8.3 million from the Bill and Melinda Gates

Foundation to develop, manufacture and validate a quantitative, low-cost, nucleic acid assay for HIV drug treatment monitoring on the

integrated Savanna MDx platform for use in limited resource settings. Upon execution of the grant agreement, the Company received $2.6 million to fund subsequent research and development activities and received milestone payments totaling $2.5 million in 2013. On September 10, 2014, the Company entered into an amended grant agreement with the Bill and Melinda Gates Foundation for additional funding of up to $12.6 million in order to accelerate the development of the Savanna MDx platform in the developing world. Upon execution of the amended grant agreement, the Company received $10.6 million in cash. The Company received payments of $2.4 million in April 2015 and $2.8 million in July 2016 based on milestone achievements for both the original and the amended grant agreements. Under the original and amended grant agreements, the Company recognized grant revenue on the basis of the lesser of the amount recognized on a proportional performance basis or the amount of cash payments that were non-refundable as of the end of each reporting period. For the years ended December 31, 2016, 2015 and 2014, the Company recognized $6.5 million, $5.1 million and $6.3 million as grant revenue, respectively. Cash payments received were restricted as to use until expenditures contemplated in the grant were incurred or committed. As of December 31, 2016, all payment related milestones have been achieved and all of the grant revenue of $20.9 million has been recorded.

Research and Development Costs—Research and development costs are charged to operations as incurred. In conjunction with certain third party service agreements, the Company is required to make periodic payments based on achievement of certain milestones. The costs related to these research and development services are also charged to operations as incurred.

Product Shipment Costs—Product shipment costs are included in sales and marketing expense in the accompanying Consolidated Statements of Operations. Shipping and handling costs were $3.8 million, $3.9 million and $3.8 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Advertising Costs—Advertising costs are expensed as incurred. Advertising costs were $0.3 million, $0.7 million and $0.4 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Deferred Rent—Rent expense is recorded on a straight-line basis over the term of the lease. The difference between rent expense and amounts paid under the lease agreement are recorded as deferred rent.

Income Taxes—Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The Company’s policy is to recognize the interest expense and penalties related to income tax matters as a component of income tax expense.

Fair Value of Financial Instruments— The Company uses the fair value hierarchy established in ASC Topic 820, Fair Value Measurements and Disclosures, that requires the valuation of assets and liabilities subject to fair value measurements using a three tiered approach and fair value measurement be classified and disclosed by the Company in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

The carrying amounts of the Company’s financial instruments, including cash, receivables, accounts payable and accrued liabilities approximate their fair values due to their short-term nature.

Product Warranty—The Company generally sells products with a limited product warranty and certain limited indemnifications. Due to product testing, the short time between product shipment and the detection and correction of product failures and a low historical rate of payments on indemnification claims, the historical activity and the related expense were not significant for the fiscal years presented.

Stock-Based Compensation—Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option. The total number of stock options expected to vest is adjusted by estimated forfeiture rates. The Company determined the estimated fair value of each stock option on the date of grant using the Black-Scholes option valuation model. Compensation expense for restricted stock units (RSUs) is measured

at the grant date and

52

recognized ratably over the vesting period. The fair value of RSUs is determined based on the closing market price of the Company's common stock on the grant date.

Computation of (Loss) Earnings Per Share—For the years ended December 31, 2016, 2015 and 2014, basic loss per share was computed by dividing net loss by the weighted-average number of common shares outstanding, including restricted stock units vested during the period. Diluted earnings per share ("EPS") reflects the potential dilution that could occur if the earnings were divided by the weighted-average number of common shares and potentially dilutive common shares from outstanding stock options as well as unvested restricted stock units. Potential dilutive common shares were calculated using the treasury stock method and represent incremental shares issuable upon exercise of the Company's outstanding stock options and unvested restricted stock units.

For the years ended December 31, 2016, 2015 and 2014, there were no differences between the number of common shares used for the basic and diluted EPS computation because the Company incurred a net loss and the effect would be anti-dilutive. Stock options and shares of restricted stock that would have been included in the diluted EPS calculation if the Company had earnings amounted to 0.8 million, 1.0 million and 1.1 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Additionally, stock options are excluded from the calculation of diluted EPS when the combined exercise price, unrecognized stock-based compensation and expected tax benefits upon exercise are greater than the average market price for the Company's common stock because their effect is anti-dilutive. Stock options totaling 2.8 million, 1.9 million and 1.0 million for the years ended December 31, 2016, 2015 and 2014, respectively, were not included in the computation of diluted EPS because the exercise of such options would be anti-dilutive.

As discussed in Note 2, the Company issued its 3.25% Convertible Senior Notes due 2020 ("Convertible Senior Notes") in December 2014. It is the Company's intent and policy to settle conversions through combination settlement, which essentially involves repayment of an amount of cash equal to the "principal portion" and delivery of the "share amount" in excess of the conversion value over the principal portion in cash or shares of common stock ("conversion premium"). No conversion premium existed as of December 31, 2016, 2015 and 2014; therefore, there was no dilutive impact from the Convertible Senior Notes to diluted EPS during the years ended December 31, 2016 2015 and 2014.

Comprehensive Loss—Comprehensive loss includes unrealized gains and losses excluded from the Company's Consolidated Statements of Operations.

Use of Estimates—The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Accounting Periods—Each of the Company's fiscal quarters end on the Sunday closest to the end of the calendar quarter. The Company's fiscal year ends are January 1, 2017, January 3, 2016 and December 28, 2014. For ease of reference, the calendar quarter end dates are used herein.

Recent Accounting Pronouncements—In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance codified in Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers, which amends the guidance in former ASC 605, Revenue Recognition. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current authoritative guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The FASB has issued several amendments to the new standard, which include clarification of accounting guidance related to identification of performance obligations, intellectual property licenses, and principal vs. agent considerations. The standard will be effective for public entities for annual reporting periods beginning after December 15, 2017, including interim periods therein.

The Company has assigned internal resources to assist in the adoption of the new standard and is in the initial stages of its evaluation of the impact of the new standard on its accounting policies, processes and system requirements. The Company has begun the process of identifying, categorizing and analyzing its various revenue streams, however, has not yet completed its assessment of the impact. The Company will continue to evaluate the future impact and method

of adoption of ASU 2014-09

53

and related amendments on the Consolidated Financial Statements and related disclosures throughout 2017. The Company will adopt the new standard beginning January 2018.

In August 2014, the FASB issued guidance codified in ASU 2014-15 (Subtopic 205-40), Presentation of Financial Statements - Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The guidance requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable). Management will be required to make this evaluation for both annual and interim reporting periods and will make certain disclosures if it concludes that substantial doubt exists or when its plans alleviate substantial doubt about the entity's ability to continue as a going concern. Substantial doubt exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). The term probable is used consistently with its use in ASC Topic 450, Contingencies. The guidance is effective for annual periods ending after December 15, 2016 and for interim reporting periods starting in the first quarter 2017, with early adoption permitted. The Company's adoption of this guidance in the annual period ended December 31, 2016 did not have an impact on the consolidated financial statements.

In February 2015, the FASB issued guidance codified in ASU 2015-02 (Topic 810), Consolidation - Amendments to the Consolidation Analysis. The guidance affects reporting entities that are required to evaluate whether they should consolidate certain legal entities. Specifically, the guidance amends (i) the identification of variable interests (fees paid to a decision maker or service provider), (ii) the variable interest entity (VIE) characteristics for a limited partnership or similar entity and (iii) the primary beneficiary determination. The guidance is effective for annual periods beginning after December 15, 2015 and for interim reporting periods starting in the first quarter 2016. The Company's adoption of this guidance in the first quarter of 2016 did not have a significant impact on the consolidated financial statements.

In July 2015, the FASB issued guidance codified in ASU 2015-11 (Topic 330), Simplifying the Measurement of Inventory. The guidance applies to inventory that is measured using first-in, first-out ("FIFO") or average cost. Under the guidance, an entity should measure inventory that is within scope at the lower of cost and net realizable value, which is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The guidance is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted as of the beginning of an interim or annual reporting period. The Company's adoption of this guidance in the first quarter of 2016 did not have a significant impact on the consolidated financial statements.

In February 2016, the FASB issued guidance codified in ASU 2016-02 (Topic 842), Leases. The guidance requires a lessee to recognize a lease liability for the obligation to make lease payments and a right-to-use asset representing the right to use the underlying asset for the lease term on the balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018 including interim periods within those years, with early adoption permitted. The Company is currently evaluating the impact of this guidance and expects to adopt the standard in the first quarter of 2019.

In March 2016, the FASB issued guidance codified in ASU 2016-09 (Topic 718), Improvements to Employee Share Based Payments Accounting. Under the guidance, entities will no longer record excess tax benefits and certain tax deficiencies in additional paid-in capital (APIC). Instead, they will record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement, and APIC pools will be eliminated. In addition, entities will recognize excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. Under current guidance, excess tax benefits are not recognized until the deduction reduces taxes payable. Companies will apply this part of the guidance using a modified retrospective transition method and will record a cumulative-effect adjustment in retained earnings for excess tax benefits not previously recognized. The guidance also allows an employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting. The guidance is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted, but all of the guidance must be adopted in the same period. The Company has excess tax benefits for which a benefit could not be previously recognized of approximately $1.8 million. Upon adoption the balance of the unrecognized excess tax benefits will be reversed with the impact recorded

to (accumulated deficit) retained earnings, including any change to the valuation allowance as a result of the adoption. Due to the full valuation allowance on the U.S. deferred tax assets as of December 31, 2016, the Company does not expect any impact to the financial statements as a result of this adoption in the first quarter of 2017.

Note 2. Debt

3.25% Convertible Senior Notes due 2020

In December 2014, the Company issued $172.5 million aggregate principal amount of 3.25% Convertible Senior Notes due 2020. Debt issuance costs of approximately $5.1 million were primarily comprised of underwriters fees, legal, accounting, and other professional fees of which $4.2 million were capitalized and are recorded as a reduction to long-term debt and are being amortized using the effective interest method to interest expense over the six-year term of the Convertible Senior Notes. The remaining $0.9 million of debt issuance costs were allocated as a component of equity in additional paid-in capital. Deferred issuance costs related to the Convertible Senior Notes were $2.8 million and $3.5 million as of December 31, 2016 and 2015, respectively.

The Convertible Senior Notes will be convertible into cash, shares of common stock, or a combination of cash and shares of common stock based on an initial conversion rate, subject to adjustment, of 31.1891 shares per $1,000 principal amount of the Convertible Senior Notes (which represents an initial conversion price of approximately $32.06 per share) on the business day immediately preceding September 15, 2020. This conversion will occur in the following circumstances and to the following extent: (1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2015, if the last reported sales price of the Company's common stock, for at least 20 trading days (whether or not consecutive) in the period of 30 consecutive trading days ending on the last trading day of the calendar quarter immediately preceding the calendar quarter in which the conversion occurs, is more than 130% of the conversion price of the notes in effect on each applicable trading day; (2) during the five consecutive business day period following any five consecutive trading day period in which the trading price per 1,000 principal amount of the Convertible Senior Note for each such trading day was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such day; or (3) upon the occurrence of specified events described in the indenture for the Convertible Senior Notes. On or after September 15, 2020 until the close of business on the second scheduled trading day immediately preceding the stated maturity date, holders may surrender their notes for conversion at any time, regardless of the foregoing circumstances.

It is the Company’s intent and policy to settle conversions through combination settlement, which essentially involves repayment of an amount of cash equal to the “principal portion” and delivery of the “share amount” in excess of the principal portion in shares of common stock or cash. In general, for each $1,000 in principal, the “principal portion” of cash upon settlement is defined as the lesser of $1,000, and the conversion value during the 25-day observation period as described in the indenture for the Convertible Senior Notes. The conversion value is the sum of the daily conversion value which is the product of the effective conversion rate divided by 25 days and the daily volume weighted average price (“VWAP”) of the Company’s common stock. The “share amount” is the cumulative “daily share amount” during the observation period, which is calculated by dividing the daily VWAP into the difference between the daily conversion value (i.e., conversion rate x daily VWAP) and $1,000.

The Company pays 3.25% interest per annum on the principal amount of the Convertible Senior Notes semi-annually in arrears in cash on June 15 and December 15 of each year. The Convertible Senior Notes mature on December 15, 2020. During the year ended December 31, 2016, the Company recorded total interest expense of $10.9 million related to the Convertible Senior Notes of which $5.4 million related to the amortization of the debt discount and issuance costs and $5.5 million related to the coupon due semi-annually. During the year ended December 31, 2015, the Company recorded total interest expense of $10.9 million related to the Convertible Senior Notes of which $5.3 million related to the amortization of the debt discount and issuance costs and $5.6 million related to the coupon due semi-annually. During the year ended December 31, 2014, the Company recorded total interest expense of $0.6 million related to the Convertible Senior Notes of which $0.3 million related to the amortization of the debt discount and issuance costs and $0.3 million related to the coupon due semi-annually.

If a fundamental change, as defined in the indenture for the Convertible Senior Notes, such as an acquisition, merger, or liquidation of the Company, occurs prior to the maturity date, subject to certain limitations, holders of the Convertible Senior Notes may require the Company to repurchase all or a portion of their Convertible Senior Notes for cash at a repurchase price equal to 100% of the principal amount of the Convertible Senior Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the repurchase date.

The Company accounts separately for the liability and equity components of the Convertible Senior Notes in accordance with authoritative guidance for convertible debt instruments that may be settled in cash upon conversion.

The guidance requires the carrying amount of the liability component to be estimated by measuring the fair value of a similar liability that does not have an associated conversion feature. Because the Company had no outstanding non-convertible public debt, the Company determined that senior, unsecured corporate bonds traded on the market represent a similar liability to the Convertible Senior Notes without the conversion option. Based on market data available for publicly traded, senior, unsecured corporate bonds issued by companies in the same industry with similar credit ratings and with similar maturity, the Company estimated the implied interest rate of its Convertible Senior Notes to be 6.9%, assuming no conversion option. Assumptions used in the estimate represent what market participants would use in pricing the liability component, which were defined as Level 2

observable inputs. The estimated implied interest rate was applied to the Convertible Senior Notes, which resulted in a fair value of the liability component of $141.9 million upon issuance, calculated as the present value of implied future payments based on the $172.5 million aggregate principal amount. The $30.7 million difference between the cash proceeds of $172.5 million and the estimated fair value of the liability component was recorded in additional paid-in capital, net of tax and issuance costs, as the Convertible Senior Notes were not considered redeemable.

In the first quarter of 2016, the Company repurchased and retired $5.2 million in principal amount of the outstanding Convertible Senior Notes. The aggregate cash used for the transaction was $4.5 million. The repurchase resulted in a reduction in debt of $4.4 million and a reduction in additional paid-in capital of $0.5 million with a gain on extinguishment of Convertible Senior Notes of $0.4 million included in interest expense, net in the Consolidated Statements of Operations.

The following table summarizes information about the equity and liability components of the Convertible Senior Notes (dollars in thousands). The fair values of the respective notes outstanding were measured based on quoted market prices.

	December 31,	
	2016	2015
Principal amount of Convertible Senior Notes outstanding	$167,314	$172,500
Unamortized discount of liability component	(20,221)	(25,703)
Unamortized deferred issuance costs	(2,753)	(3,500)
Net carrying amount of liability component	144,340	143,297
Less: current portion	—	—
Long-term debt	$144,340	$143,297
Carrying value of equity component, net of issuance costs	$29,211	$29,758
Fair value of outstanding Convertible Senior Notes	$165,223	$170,120
Remaining amortization period of discount on the liability component	4 years	5 years

As a policy election under applicable guidance related to the calculation of diluted net EPS, the Company elected the combination settlement method as its stated settlement policy and applied the treasury stock method in the calculation of dilutive impact of the Convertible Senior Notes. The Convertible Senior Notes were not convertible as of the years ended December 31, 2016, 2015 and 2014; therefore there was no dilutive impact during the years ended December 31, 2016, 2015 and 2014. If the Convertible Senior Notes were converted as of December 31, 2016, the if-converted value would not exceed the principal amount.

Line of Credit

On August 10, 2012, the Company entered into an amended and restated $140.0 million senior secured syndicated credit facility (the “Senior Credit Facility”), which was set to mature on August 10, 2017. In connection with this agreement, the Company incurred an additional $1.0 million in deferred financing costs related to the Senior Credit Facility. Deferred financing costs were amortized on a straight-line basis over the term of the Senior Credit Facility and were included as a portion of prepaid expenses and other current assets. On December 1, 2016, the Company voluntarily terminated its Senior Credit Facility and wrote off unamortized deferred financing costs of $0.2 million, which was included in interest expense, net in the Consolidated Statements of Operations for the year ended December 31, 2016. As of December 31, 2015, $0.2 million of deferred financing costs were included as a portion of other non-current assets and $0.3 million were included as a portion of prepaid expenses and other current assets.

Note 3. Income Taxes

Significant components of the (benefit) provision for income taxes are as follows (in thousands):

	December 31,		
	2016	2015	2014
Current:			
Federal	$(117)	$948	$61
State	246	399	(1,294)
Foreign	84	41	69
Total current provision (benefit)	213	1,388	(1,164)
Deferred:			
Federal	(2,545)	(4,624)	(5,267)
State	(63)	—	2,488
Foreign	4	18	34
Total deferred benefit	(2,604)	(4,606)	(2,745)
Benefit for income taxes	$(2,391)	$(3,218)	$(3,909)

The Company's (loss) income before (benefit) provision for income taxes was subject to taxes in the following jurisdictions for the following periods (in thousands):

	December 31,		
	2016	2015	2014
United States	$(16,426)	$(9,480)	$(11,328)
Foreign	227	183	345
Loss before benefit for income taxes	$(16,199)	$(9,297)	$(10,983)

Significant components of the Company's deferred tax assets and deferred tax liabilities as of December 31, 2016 and 2015 are shown below (in thousands).

	December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	$3,255	$1,199
Intangible assets	2,351	3,574
Sale-leaseback, net	888	1,224
Allowance for returns and discounts	4,043	4,308
Stock-based compensation	10,963	9,884
Tax credit carryforwards	3,430	2,341
Other, net	4,066	5,200
Total deferred tax assets	28,996	27,730
Valuation allowance for deferred tax assets	(7,774)	(3,087)
Total deferred tax assets, net of valuation allowance	21,222	24,643
Deferred tax liabilities:		
Convertible Senior Notes	(7,592)	(9,474)
Intangible assets	(7,557)	(9,977)
Property, plant and equipment	(6,131)	(7,162)
Total deferred tax liabilities	(21,280)	(26,613)
Net deferred tax liabilities	$(58)	$(1,970)

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative before-tax loss incurred over the three-year periods ended December 31, 2016 and 2015. Such objective evidence

limits the ability to consider other subjective evidence such as the Company's projections for future profitability. On the basis of this evaluation, as of December 31, 2016, the Company had recorded a valuation allowance of $7.8 million, which represents the portion of the deferred tax asset that management could no longer conclude was more likely or not to be realized. The amount of the deferred tax assets considered realizable, however, could be adjusted in the future based on changes in available evidence and additional weight may be given to subjective evidence such as the Company's projections for profitability. During the year ended December 31, 2016, the allowance increased by $4.7 million.

The Company recognizes excess tax benefits associated with the exercise of stock options directly to stockholders' equity only when realized. Accordingly, deferred tax assets are not recognized for net operating loss ("NOL") carryforwards resulting from excess tax benefits. As of December 31, 2016 and 2015, deferred tax assets do not include $1.8 million and $1.3 million, respectively, of these excess tax benefits from employee stock option exercises that are a component of the Company's NOL and tax credit carryforwards. Additional paid-in capital will be increased up to an additional $1.8 million if such excess tax benefits are realized. As discussed in Note 1, upon adoption of ASU 2016-09 in the first quarter of 2017, the balance of the unrecognized excess tax benefits will be reversed with the impact recorded to (accumulated deficit) retained earnings, including any change to the valuation allowance as a result of the adoption. Due to the full valuation allowance on the U.S. deferred tax assets as of December 31, 2016, the Company does not expect any impact to the financial statements as a result of this adoption in the first quarter of 2017.

As of December 31, 2016, the Company had federal NOL carryforwards of approximately $8.3 million which will begin to expire in 2018, unless previously utilized. The Company also had state NOLs of approximately $22.8 million which will begin to expire in 2026, unless previously utilized. The Company has federal research credits of $3.7 million which will begin to expire on December 31, 2031, unless previously utilized. Additionally, the Company has federal alternative minimum tax credits of $0.5 million which do not expire. The Company also has gross state research credits of $8.9 million, of which $8.7 million do not expire. The remaining $0.2 million begin to expire in 2027, unless previously utilized.

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, the Company's use of its NOL and research credit carryforwards may be limited as a result of cumulative changes in ownership of more than 50% over a three-year period.

The benefit for income taxes reconciles to the amount computed by applying the federal statutory rate to loss before taxes as follows (in thousands):

	Year ended December 31,		
	2016	2015	2014
Tax benefit at statutory tax rate	(5,775)	(3,254)	(3,844)
State tax benefit, net of federal tax benefit	(390)	(235)	(151)
Permanent differences	129	157	70
Federal and state research credits—current year	(979)	(722)	(765)
Accrual (release) of uncertain tax positions	43	101	(21)
Expiration of statutes for uncertain tax positions	—	—	(953)
Impact of change in federal and state tax rate on revaluing deferred tax assets	(4)	56	110
Change in valuation allowance	4,687	756	2,331
Acquisition related adjustments	—	—	(485)
Other	(102)	(77)	(201)
Benefit for income taxes	(2,391)	(3,218)	(3,909)

On December 18, 2015, the Protecting Americans from Tax Hikes Act was signed into law reinstating the federal research and development credit for 2015. Accordingly, we recorded the benefit related to the 2015 federal research and development credit of approximately $0.4 million in the fourth quarter of 2015.

The Company considers earnings of its non-U.S. subsidiaries to be indefinitely reinvested in those operations. As of December 31, 2016, the Company has not made a provision for U.S. or additional foreign withholding taxes on

approximately $0.5 million of the excess of the amount for financial reporting over the tax basis of investments in foreign subsidiaries that is indefinitely reinvested. Generally, such amounts become subject to U.S. taxation upon the remittance of dividends and under certain other circumstances. It is not practicable to estimate the amount of deferred tax liability related to investments in these foreign subsidiaries.

The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes that it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcome of examinations by tax authorities in determining the adequacy of its provision for income taxes.

The following table summarizes the activity related to the Company's unrecognized tax benefits (in thousands):

	Year ended December 31,		
	2016	2015	2014
Beginning balance	$7,684	$7,065	$7,765
Decreases related to prior year tax positions	(10)	(12)	(68)
Increases related to current year tax positions	773	631	642
Decreases due to settlements	—	—	(42)
Expiration of the statute of limitations for the assessment of taxes	—	—	(1,232)
Other	$157	$—	$—
Ending balance	$8,604	$7,684	$7,065

As of December 31, 2016 and 2015, the unrecognized tax benefits of $8.6 million and $7.7 million, respectively, of which $6.4 million and $5.6 million, respectively, would reduce the Company's annual effective tax rate, subject to the valuation allowance. The Company does not anticipate any significant decreases in its unrecognized tax benefits over the next 12 months. The Company's policy is to recognize the interest expense and penalties related to income tax matters as a component of income tax expense. The Company has accrued approximately $0.2 million of interest and penalties associated with uncertain tax positions for each of the years ended December 31, 2016 and 2015. There was no interest expense, net of accrued interest (reversed) in 2016. Interest expense, net of accrued interest (reversed) was approximately $0.1 million, and $(0.2) million in 2015 and 2014, respectively.

The Company is subject to periodic audits by domestic and foreign tax authorities. During 2014, the Company released tax reserves and related interest of approximately $1.0 million, net of federal income tax benefits, related to the expiration of the statute of limitation on assessment for certain state matters.

Due to the carryforward of unutilized net operating loss and credit carryovers, the Company's federal tax years from 2009 and forward and state tax years 2001 and forward are subject to examination by tax authorities.

The Company believes that it has appropriate support for the income tax positions taken on its tax returns and that its accruals for tax liabilities are adequate for all open years based on an assessment of many factors, including past experience and interpretations of tax law applied to the facts of each matter.

Note 4. Stockholders' Equity

Preferred Stock. The Company's certificate of incorporation, as amended, authorizes the issuance of up to five million preferred shares. The Board of Directors is authorized to fix the number of shares of any series of preferred stock and to determine the designation of such shares. However, the amended certificate of incorporation specifies the initial series and the rights of that series. No shares of preferred stock were outstanding as of December 31, 2016, 2015 or 2014.

Equity Incentive Plan. The Company grants stock options, time-based restricted stock units (RSUs) and performance-based restricted stock units (PSUs) to employees and non-employee directors under its 2016 Equity Incentive Plan (the "2016 Plan"). The Company previously granted stock options under the Amended and Restated 2010 Equity Incentive Plan (the "2010 Plan") and the Amended and Restated 2001 Equity Incentive Plan (the "2001 Plan"). The 2010 Plan and 2001 Plan were terminated at the time of adoption of the new Plans, but the terminated Plans continue to govern outstanding options granted thereunder. The Company has stock options and RSUs outstanding, which were issued under each of these equity incentive plans to certain employees and directors. Stock options granted under these plans have terms ranging up to ten years, have exercise prices ranging from $8.50 to $27.91 per share, and generally vest over four years. As of December 31, 2016, approximately 2.6 million shares remained available for grant under the 2016 Plan.

59

Restricted Stock. The Company grants time-based RSUs and PSUs to certain officers, directors and management. Until the restrictions lapse, ownership of the affected RSUs and PSUs granted to the Company's officers is conditional upon continuous employment with the Company.

For the years ended December 31, 2016, 2015 and 2014, the Company granted approximately 0.2 million, 0.2 million and 0.1 million shares, respectively, of RSUs to officers and management, which have a time-based four-year vesting provision. For purposes of measuring compensation expense of PSUs, the amount of shares ultimately expected to vest is estimated at each reporting date based on management's expectations regarding the relevant performance criteria. The recognition of compensation expense associated with the PSUs requires judgment in assessing the probability of meeting the performance goals, as well as defined criteria for assessing achievement of the performance-related goals. The grant date of the PSUs takes place when the grant is authorized and the specific achievement goals are communicated. The communication date of the performance goals can impact the valuation and associated expense of the PSUs.

PSUs granted in March 2012 included a three-year vesting cliff based on the achievement of a performance metric tied to earnings per share for the year ended December 31, 2014. During the fourth quarter ended December 31, 2014, the Compensation Committee of the Board of Directors amended the performance metric to include adjustments for certain items, some of which are non-recurring. This resulted in a modification of the original award and the Company recorded additional stock-based compensation expense of $0.3 million for the year ended December 31, 2014. The PSUs granted in March 2012 were released in March 2015 as performance metrics were achieved. There were no PSUs outstanding as of December 31, 2016 or December 31, 2015.

During the years ended December 31, 2016, 2015 and 2014, RSUs were granted to certain members of the Board of Directors in lieu of cash compensation as a part of the Company's non-employee director's deferred compensation program. The compensation expense associated with these RSU grants were $0.4 million, $0.5 million and $0.4 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Employee Deferred Bonus Compensation Program. For the years ended December 31, 2016, 2015 and 2014, certain employees of the Company were eligible to participate in the Company's deferred bonus compensation program with respect to any payments received under the Company's cash incentive plan. Participating employees could elect to receive 50% or 100% of the cash value of their cash bonus in the form of fully vested, restricted stock units plus an additional premium as additional restricted stock units, issued under the 2016 Plan. The premium restricted stock units are subject to a one-year vesting requirement from the date of issuance.

The additional premium will be determined based on the length of time of the deferral period selected by the participating employee as follows: (i) if one year from the date of grant, a premium of 10% on the amount deferred, (ii) if two years from the date of grant, a premium of 20% on the amount deferred, or (iii) if four years from the date of grant, a premium of 30% on the amount deferred.

Employee Stock Purchase Plan. Under the Company's Amended and Restated 1983 Employee Stock Purchase Plan (the "ESPP"), full-time employees are allowed to purchase common stock through payroll deductions (which cannot exceed 10% of the employee's compensation) at the lower of 85% of fair market value at the beginning or end of each six-month purchase period. As of December 31, 2016, 1,214,175 shares had been sold under the Plan, leaving 285,825 shares available for future issuance.

Share Repurchase Program. On January 25, 2016, our Board of Directors authorized an amendment to extend our previously announced stock repurchase program. The Board of Directors has authorized the Company to repurchase up to an aggregate of $50.0 million in shares of our common stock under our stock repurchase program. Any shares of common stock repurchased under this program will no longer be deemed outstanding upon repurchase and will be returned to the pool of authorized shares. During the year ended December 31, 2016, 1,152,386 shares of outstanding common stock were repurchased under the Company's previously announced share repurchase program for approximately $19.6 million. At December 31, 2016, $35.0 million remains available under this program. The repurchase program will expire on January 25, 2018 unless extended by the Board of Directors.

Shares Reserved for Future Issuance. At December 31, 2016, approximately 7.0 million shares of common stock were reserved under the Company's equity incentive plans and 285,825 shares were reserved for purchases under the ESPP.

Note 5. Stock-Based Compensation

For the years ended December 31, 2016, 2015 and 2014 stock-based compensation expense was $8.0 million, $7.4 million and $6.7 million, respectively, of which $4.7 million, $4.7 million and $4.3 million, respectively, related to stock options and $2.4 million, $2.0 million and $2.1 million, respectively, related to RSUs and PSUs. For the years ended December 31, 2016, 2015 and 2014 the Company recorded $0.9 million, $0.7 million and $0.3 million in stock-based compensation expense, respectively, associated with the deferred bonus compensation program, described in Note 4. During the years ended December 31, 2016, 2015 and 2014, $0.9 million, $0.6 million and $0.3 million, respectively, were initially recorded as a component of accrued payroll and related expenses.

Stock-based compensation expense related to stock options, RSUs and PSUs was as follows (in thousands):

	Year ended December 31,		
	2016	2015	2014
Cost of sales	$617	$581	$609
Research and development	1,551	734	1,062
Sales and marketing	1,189	1,554	1,059
General and administrative	4,629	4,550	3,994
	$7,986	$7,419	$6,724

Stock-based compensation expense capitalized to inventory and compensation expense related to the Company's ESPP were not material for the years ended December 31, 2016, 2015 and 2014.

Stock Options

Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option award. For stock options with graded vesting, the Company ensures that the cumulative amount of compensation expense recognized at the end of any reporting period at least equals the portion of the stock option that has vested at that date. The total number of stock options expected to vest is adjusted by estimated forfeiture rates. The estimated fair value of each stock option was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for the option grants:

	Year ended December 31,		
	2016	2015	2014
Risk-free interest rate	1.47%	1.50%	1.59%
Expected option life (in years)	6.59	6.24	5.78
Volatility rate	36 %	40 %	42 %
Dividend rate	— %	— %	— %

The computation of the expected option life is based on a weighted-average calculation combining the average life of options that have already been exercised and post-vest cancellations with the estimated life of the remaining vested and unexercised options. The expected volatility is based on the historical volatility of the Company's stock. The risk-free interest rate is based on the U.S. Treasury yield curve over the expected term of the option. The Company has never paid any cash dividends on its common stock, and does not anticipate paying any cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield of zero in the Black-Scholes option valuation model. The Company's estimated forfeiture rate is based on its historical experience and future expectations. The Company's determination of fair value is affected by the Company's stock price as well as a number of assumptions that require judgment. The weighted-average fair value per share was $6.00, $9.46 and $10.96 for options granted during the years ended December 31, 2016, 2015 and 2014, respectively. The total intrinsic value was $4.5 million, $1.6 million and $2.8 million for options exercised during the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, total unrecognized compensation expense related to stock options was approximately $5.8 million and the related weighted-average period over which it is expected to be recognized is approximately 2.2 years. The maximum contractual term of the Company's stock options is ten years.

A summary of the status of stock option activity for the years ended December 31, 2014, 2015 and 2016 is as follows (in thousands, except price data and years):

	Number of Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at January 1, 2014	3,474	$ 14.74		
Granted	559	26.63		
Exercised	(251)	13.67		
Cancelled	(175)	20.63		
Outstanding at December 31, 2014	3,607	16.37		
Granted	659	23.15		
Exercised	(168)	12.30		
Cancelled	(131)	23.41		
Outstanding at December 31, 2015	3,967	17.44		
Granted	677	15.48		
Exercised	(553)	13.76		
Cancelled	(150)	20.86		
Outstanding at December 31, 2016	3,941	$ 17.49	5.52	$ 19,236
Vested and expected to vest at December 31, 2016	3,781	$ 17.45	5.38	$ 18,590
Exercisable at December 31, 2016	2,529	$ 15.92	3.95	$ 15,451
Available for future grant at December 31, 2016	2,572			

Restricted Stock Units

The Company grants both time-based RSUs and PSUs. The fair value of RSUs and PSUs is determined based on the closing market price of the Company's common stock on the grant date. Compensation expense for RSUs is measured at the grant date and recognized ratably over the vesting period. A portion of the restricted stock granted in 2012 was performance-based and vesting was tied to achievement of specific Company goals in 2014. For purposes of measuring compensation expense for PSUs, the amount of shares ultimately expected to vest was estimated at each reporting date based on management's expectations regarding the relevant performance criteria. The recognition of compensation expense associated with the PSUs required judgment in assessing the probability of meeting the performance goals, as well as defined criteria for assessing achievement of the performance-related goals. The PSUs granted in March 2012 were released in March 2015. See further discussion of amended performance metrics and the impact to stock-based compensation expense for the year ended December 31, 2014 in Note 4. There was no stock-based compensation expense related to PSUs for the years ended December 31, 2016 or 2015.

A summary of the status of stock awards activity for the years ended December 31, 2014, 2015 and 2016 is as follows (in thousands, except price data):

	Shares	Weighted-average grant date fair value
Non-vested at January 1, 2014	454	$ 16.22
Granted	145	25.73
Vested	(174)	28.27
Forfeited	(23)	18.19
Non-vested at December 31, 2014	402	14.84
Granted	171	22.79
Vested	(96)	18.01
Forfeited	(18)	22.87
Non-vested at December 31, 2015	459	21.61
Granted	185	16.14
Vested	(120)	18.50
Forfeited	(23)	20.80
Non-vested at December 31, 2016	501	$ 20.37

In 2016, 2015 and 2014, the Company issued approximately 0.1 million restricted share units each year in exchange for the deferred bonus liability of $0.5 million, $0.4 million and $0.7 million, respectively.

The total amount of unrecognized compensation expense related to non-vested stock awards as of December 31, 2016 was approximately $3.1 million, which is expected to be recognized over a weighted-average period of approximately 2.4 years.

Note 6. Commitments and Contingencies

Leases

The Company leases its facilities and certain equipment. Commitments for minimum rentals under non-cancelable leases at the end of 2016 are as follows (in thousands):

Years ending December 31,	Operating Leases	Lease obligation
2017	$ 2,245	$ 937
2018	2,296	946
2019	2,342	956
2020	2,365	967
2021	2,261	—
Thereafter	625	—
Total minimum lease payments	$ 12,134	$ 3,806

Operating Leases—Rent expense under operating leases totaled approximately $2.2 million for the year ended December 31, 2016, $2.3 million for the year ended December 31, 2015 and $3.3 million for the year ended December 31, 2014.

In the fourth quarter of 2013, the Company entered into a lease for approximately 30,000 square feet of office space and moved the executive and administrative functions into this facility in the second quarter of 2014. The lease expires in 2022 with options to extend the lease for two additional five-year periods. This operating lease included a lease incentive for tenant improvements of $1.7 million which has been included as a leasehold improvement in property, plant and equipment and as deferred rent in other current liabilities and non-current deferred rent.

McKellar Lease Obligation—During 1999, the Company completed a sale and leaseback transaction of its San Diego facility. The facility was sold for $15.0 million, of which $3.8 million was capital contributed by the Company. The sale was an all cash transaction, netting the Company approximately $7.0 million. The Company is a 25% limited partner in the partnership that acquired the facility. The transaction was deemed a financing transaction under the guidance in ASC Topic 840-40, Accounting for Sales of Real Estate. The assets sold remain on the books of the Company and will continue to be depreciated over the estimated useful life. In December 2009, the Company amended the terms of its lease agreement which had no significant impact on the Company's financial statements. The amended terms included a new ten-year lease term through December 31, 2019, with options to extend the lease for up to three additional five-year periods.

In the fourth quarter of 2015, the Company amended the terms of its lease agreement to extend the lease term through December 31, 2020. The options to extend the lease for up to three additional five-year periods commence at the new lease term date of December 31, 2020. The Company is amortizing the lease obligation over the new estimated lease term, including extensions. As the Company accounts for the lease as a financing transaction, the Company adjusted the implied interest rate so that the existing lease obligation is amortized to the end of the estimated lease term, including extensions. The Company has determined that the partnership is a variable interest entity (VIE). The Company is not, however, the primary beneficiary of the VIE as it does not absorb the majority of the partnership's expected losses or receive a majority of the partnership's residual returns. The Company made lease payments to the partnership of approximately $0.9 million, $1.1 million and $1.1 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Purchase Commitments

The Company has $4.3 million in firm purchase commitments with respect to planned inventory and capital expenditures as of December 31, 2016.

Legal

The Company is involved in various claims and litigation matters from time to time in the ordinary course of business. Management believes that all such current legal actions, in the aggregate, will not have a material adverse effect on the Company. The Company also maintains insurance, including coverage for product liability claims, in amounts which management believes are appropriate given the nature of its business. No accrual has been recorded as of December 31, 2016 related to such matters as they are not probable and/or reasonably estimable. At December 31, 2015, the Company had $0.2 million accrued as a liability for various legal matters where the Company deemed the liability probable and estimable.

Licensing Arrangements

On September 27, 2011, the Company entered into the Second Amendment (the "Amendment") to Quidel/Inverness Settlement Agreement dated April 27, 2005 (the "Agreement"), as amended by an Addendum dated June 19, 2006, with Alere Inc. (formerly known as Inverness Medical Innovations, Inc.) ("Alere").

The Amendment, which was effective as of April 1, 2011, amended certain royalty and other provisions in the Agreement and enabled the Company to "buy-down" and "buy-out" its future royalty obligation under the Agreement for payments totaling $29.5 million. Under the Amendment, the Company made an initial cash payment of $13.8 million to Alere in September 2011 in connection with a buy-down of the Company's royalty obligations for the period beginning July 1, 2011. In addition, the Company exercised its buy-out right for any remaining future royalty obligation by exercising the Royalty Termination Option (as defined in the Amendment) in January 2012, thereby terminating the Company's obligation to pay future royalties under the Agreement in exchange for a fixed cash payment in the amount of $15.7 million less $1.0 million of specified third quarter 2011 royalties. This amount was paid in February 2012.

In conjunction with Financial Accounting Standards Board Accounting Standard Update No. 2009-05, Fair Value Measurements and Disclosures (Topic 820), the Company assigned $28.8 million to the licensed technology and $0.7 million as a one-time charge to cost of sales to settle royalty claims. In determining the fair value allocation between the intangible asset licensed technology and the one-time charge to cost of sales, the Company assessed the past and estimated future revenue streams related to present and future products that use the patents that were subject to the Amendment. The effective life and related amortization of the licensed technology was based on the higher of the percentage of usage or the straight-line method. This percentage of usage was determined using the revenues

generated from products covered by the patents that were subject to the Amendment. The terms of the Amendment provide for an estimated useful life of 3.5 years for this asset. The Company recorded $0.7 million of amortization expense in 2015 and $8.0 million in 2014, included as a portion of cost of sales. As of December 31, 2015, this intangible asset has been fully amortized.

In addition to the royalty agreement noted above, the Company has entered into various other licensing and royalty agreements, which largely require payments based on specified product sales as well as the achievement of specified milestones. The Company had royalty and license expenses relating to those agreements of approximately $0.8 million, $0.5 million and $0.9 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Research and Development Agreements

The Company has entered into various research and development agreements that provide it with rights to develop, manufacture and market products using the intellectual property and technology of its collaborative partners. Under the terms of certain of these agreements, the Company is required to make periodic payments based on achievement of certain milestones or resource expenditures. These milestones generally include achievement of prototype assays, validation lots and clinical trials. At December 31, 2016, total future commitments under the terms of these agreements are estimated at $2.3 million. The commitments will fluctuate as the Company agrees to new phases of development under the existing arrangements.

Contingent Consideration

In conjunction with the acquisition of BioHelix Corporation (“BioHelix”) in May 2013, the Company agreed to contingent consideration ranging from $5.0 million to $10.0 million upon achievement of certain revenue targets through May 2018. The fair value of the royalty revenue earn-out to be settled in cash is estimated using a discounted revenue model. Due to changes in the estimated payments and a shorter discounting period, the fair value of the contingent consideration liabilities changed, resulting in gains of $0.6 million, $21,000 and $0.8 million recorded to cost of sales in the Consolidated Statements of Operations during the years ended December 31, 2016, 2015 and 2014, respectively. Payments of $0.2 million and $0.1 million related to the revenue royalty earn-out were disbursed during the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, the current portion of the contingent consideration is $2.7 million and the non-current portion of the contingent consideration is $1.9 million.

In August 2013, the Company acquired the assets of AnDiaTec GmbH & Co. KG (“AnDiaTec”), a privately-held, diagnostics company, based in Germany. The Company agreed to contingent consideration of up to €0.5 million ($0.5 million based on the December 31, 2016 currency conversion rate) upon achievement of certain revenue targets through 2018. As of December 31, 2016, the Company has included $0.1 million in the non-current portion of contingent consideration related to these revenue targets. In addition, the Company agreed to pay the founder of AnDiaTec contingent payments of up to €3.0 million ($3.1 million based on the December 31, 2016 currency conversion rate) upon achievement of certain research and development milestones, subject to continued employment. The Company paid $0.9 million and $1.7 million for the achievement of agreed upon research and development milestones during the years ended December 31, 2016 and 2015, respectively. These costs are recorded as compensation expense included in research and development expense in the Consolidated Statements of Operations. As of December 31, 2016, there are no remaining research and development milestones to be achieved.

The Company recorded contingent consideration of $0.4 million related to the acquisition of Immutopics, Inc. ("Immutopics") in March 2016 as discussed in Note 11. In the fourth quarter of 2016, due to changes in the estimated payments, the Company recorded a $0.1 million loss due to the fair value adjustment.

Note 7. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented 17%, 14% and 13% of total revenue for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016 and 2015, balances due from foreign customers, in U.S. dollars, were $6.8 million and $5.6 million, respectively.

The Company had sales to individual customers in excess of 10% of total revenue, as follows:

	Year ended December 31,		
	2016	2015	2014
Customer:			
A	16%	20%	19%
B	15%	17%	18%
C	13%	11%	11%
	44%	48%	48%

65

As of December 31, 2016 and 2015, accounts receivable from individual customers with balances due in excess of 10% of total accounts receivable totaled $13.9 million and $12.0 million, respectively.

The following presents long-lived assets (excluding intangible assets) and total net revenue by geographic territory (in thousands):

	Long-lived assets as of December 31,		Total revenue for the years ended December 31,		
	2016	2015	2016	2015	2014
Domestic	$ 50,774	$ 52,426	$158,244	$168,809	$159,845
Foreign	84	121	33,359	27,320	24,313
	$ 50,858	$ 52,547	$191,603	$196,129	$184,158

Consolidated net revenues by product category are as follows (in thousands):

	Year ended December 31,		
	2016	2015	2014
Immunoassays	$121,416	$130,348	$118,715
Molecular	9,506	5,424	3,418
Virology	40,083	43,747	44,771
Specialty products	9,387	9,001	7,779
Royalties, grants and other	11,211	7,609	9,475
	$191,603	$196,129	$184,158

Note 8. Fair Value Measurement

The following table presents the Company’s hierarchy for its assets and liabilities measured at fair value on a recurring basis as of the following periods (in thousands):

	December 31, 2016				December 31, 2015			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Cash equivalents	133,540	—	—	133,540	133,147	—	—	133,147
Total assets measured at fair value	$133,540	$ —	$ —	$133,540	$133,147	$ —	$ —	$133,147
Liabilities:								
Contingent consideration	—	—	5,175	5,175	—			