QUIDEL CORP /DE/
Form 10-K
February 24, 2015

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, 2014
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 (State or other jurisdiction of incorporation or organization)	94-2573850 (I.R.S. Employer Identification No.)
12544 High Bluff Drive, Suite 200 San Diego, California (Address of principal executive offices)	92130 (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 x No ¨

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.

Large accelerated filer	x		Accelerated filer	¨
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 $631,129,950 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 19, 2015, 34,462,148 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 2015 Annual Meeting of Stockholders (to be held on May 5, 2015) are incorporated by reference into Part III, Items 10, 11, 12, 13 and 14 of this Annual Report on Form 10-K

Table of Contents

		Page
	Forward-Looking Statements	3
Part I		
Item 1.	Business	4
Item 1A.	Risk Factors	12
Item 1B.	Unresolved Staff Comments	24
Item 2.	Properties	24
Item 3.	Legal Proceedings	25
Item 4.	Mine Safety Disclosures	26
Part II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	27
Item 6.	Selected Financial Data	30
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	31
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	44
Item 8.	Financial Statements and Supplementary Data	45
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	74
Item 9A.	Controls and Procedures	74
Item 9B.	Other Information	77
Part III		
Item 10.	Directors, Executive Officers and Corporate Governance	77
Item 11.	Executive Compensation	77
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	77
Item 13.	Certain Relationships and Related Transactions, and Director Independence	77
Item 14.	Principal Accountant Fees and Services	77
Part IV		
Item 15.	Exhibits and Financial Statement Schedules	77
	Signatures	81

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, and 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 health care 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; limitations and covenants in our Senior Credit Facility; 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 US markets; our significant debt service requirements; the possibility that we may incur additional indebtedness; 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; 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," "future," a 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, including projections about our revenue, gross margins, and expenses; 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 and objectives; that point-of-care testing is increasing; that we will continue to make substantial expenditures for research and development activities; our reliance on key distributors; 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; our exposure to claims and litigation; our intention to not pay dividends; expectations regarding grant revenues and expenditures in 2015; that we will continue to incur substantial royalty and license expenses; the impact on our tax rate due to changes in California law; 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. The following should be read in conjunction with the audited Consolidated Financial Statements and Notes thereto. 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 primarily include applications in infectious diseases, women’s health and gastrointestinal diseases. 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 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, autoimmune diseases, bone health, thyroid diseases, and fecal occult blood. In February 2010, we expanded our operations through the acquisition of Diagnostic Hybrids, Inc. (“DHI”), a privately-held, in vitro diagnostics (“IVD”) company, based in Athens, Ohio. DHI is a market leader in the manufacturing and commercialization of FDA cleared direct fluorescent IVD assays used in hospitals and reference laboratories for a variety of diseases, including certain viral infections and thyroid diseases. In 2013, we completed two further acquisitions, acquiring the stock of BioHelix Corporation (“BioHelix”), a developer and manufacturer of isothermal molecular assays and enzymes, in May 2013, and acquiring the assets of AnDiaTec GmbH (“AnDiaTec”), a German based developer and manufacturer of molecular assays, in August 2013.

Corporate Information

We are a corporation, incorporated 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 more 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 three parts:

- rapid point of care immunoassay tests for use in physician offices, hospital laboratories and emergency departments, retail clinics, and other urgent care settings;
- direct fluorescent assays (“DFA”) and culture-based tests for the clinical virology laboratory; and
- molecular diagnostic tests across a number of laboratory and other segments.

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® Analyzer;

- 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 and women's health 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;
- 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 effort to create a 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 IVD products are primarily centralized laboratories and physician offices and decentralized point-of-care settings.

Centralized testing market

The centralized 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+®, MicroVue™, FreshCells™, D3 FastPoint®, Super E-Mix™, ELVIS®, Sofia®, Quidel® Molecular, Amplivue®, Lyra® and Thyretain®.

System Platforms—New and In Development:

Our diagnostic testing solutions are provided through a number of proprietary platforms, including the following platforms recently developed or in development:

Fluorescent Immunoassays

Sofia Analyzer. Sofia is the brand name for our next generation 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.

Molecular Assays

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.

Molecular Systems in Development

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.

Solana. We are developing the Solana system as an extension to the Amplivue product line, running the same proprietary HDA technology. Solana will be an easy to run amplification and detection system that will have the ability to concurrently run up to 12 assays. With minimal sample preparation for Solana assays, the system has the potential to receive a CLIA waiver.

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, during 2013, we began selling our Quidel Molecular Influenza A+B assay for use on the QuantStudio™ Dx Real-Time PCR Instruments by Life Technologies.

Streptococci. 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. Also, in late 2013, we began selling our AmpliVue Group B Strep Assay. In 2014, we began selling our AmpliVue Group A Strep Assays. In 2014, we also received FDA clearance, via the de novo request procedure, for our Lyra Direct Strep Assay, a multiplex real-time PCR assay that detects and differentiates between pyogenic Group A and pyogenic C or G Streptococcal throat infections.

RSV Test. Our Sofia RSV test and our QuickVue RSV test are rapid immunoassay tests for Respiratory Syncytial Virus ("RSV"). During 2013, we also began selling our Quidel Molecular RSV + human metapneumovirus (hMPV) test, and our Quidel Molecular Influenza A+B assay and our combo Quidel Molecular RSV + hMPV assay, both for use on the QuantStudio ™ Dx Real-Time PCR Instruments by Life Technologies. 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.

Multiplex Respiratory. Our cell culture and DFA detection solutions are used by reference laboratories, public health labs and acute care hospitals to detect seven major viral respiratory pathogens. Our proprietary cell culture platform R-Mix™ combined with our FDA cleared antibody kit D3 Ultra DFA, 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. In 2009, we introduced a new FDA cleared technology called D3 FastPoint that detects eight viruses, with human metapnuemovirus added to the testing menu. D3 FastPoint provides laboratories, in a direct specimen testing format, the ability to produce virus identification in less than 25 minutes from specimen receipt.

In 2014, we launched our 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.

General 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 normal human viruses. We provide cell-based products under the FreshCells brand in multiple different formats, including tubes, shell vials and multi-well plates.

Herpes and Herpes Family. Our proprietary engineered cell culture system, ELVIS HSV, is an FDA cleared and highly sensitive system for the isolation and detection of Herpes Simplex Virus ("HSV") types 1 and 2. Herpes is a widespread sexually transmitted infection with an HSV 2 prevalence rate of 16% of the population according to the Centers for Disease Control ("CDC"). We also provide a multiplex cell culture solution using a propriety cell platform called H&V-Mix™ that is used to isolate HSV, Varicella-Zoster Virus ("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. During 2014, we also began commercializing our Lyra Direct HSV 1+2/VZV assay and AmpliVue HSV 1+2 for the differentiation and detection of herpes simplex viruses 1 and 2 (HSV 1+2) and Varicella-Zoster Virus in active lesions within the United States.

POC Women's 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.

Bone Health. Osteoporosis is a systemic skeletal disease characterized by low bone mass and deterioration of the micro-architecture 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 (C. diff). Our Quidel Molecular Direct C. diff assay is approved for use with the Life Technologies QuantStudio Dx™ and 7500 Fast Dx Applied Biosystems® Real-Time PCR Instruments. We also sell our *C. diff* assay as part of our expanding AmpliVue product line. *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.

Immunoassay fecal occult blood. Our QuickVue test is a rapid, fecal immunochemical test ("FIT") 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. We launched our first FIT test in late December 2005.

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.

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 rapid test is a serological test that measures antibodies circulating in the blood caused by the immune response to the H. pylori bacterium.

Bone Health, Autoimmune Disease and Oncology

Our Specialty Products Group ("SPG") business develops diagnostic and research products in the fields of oncology, bone health and autoimmune disease. Assays are developed on a microwell platform and are currently marketed to clinicians and researchers. SPG is strategically focused on identifying and demonstrating clinical utility around these markers in a variety of disease states. 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. We currently sell these products both directly and through select distributors throughout the world under the Quidel and MicroVue brands. During the fourth quarter of 2013, we completed the relocation of our SPG manufacturing and research and development operations previously based in Santa Clara, California to our Athens, Ohio facility. Our SPG revenues, income and assets are less than 10% of our overall operations.

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, 2014, 2013 and 2012, 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 $37.9 million, $34.2 million, and $27.7 million for the years ended December 31, 2014, 2013 and 2012, 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 the POC clinicians located in small doctor's office practices to moderately complex physician office laboratories ("POL") 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 show 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 needs to accommodate 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.

The sales, distribution and service of our highly complex diagnostic tests are controlled primarily by us. Laboratory end-users in hospitals and clinical reference laboratories utilizing our highly complex 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.

During 2013, we continued to invest in several key areas: support for clinical research and expanding our communications through promotional campaigns, peer-reviewed technical publications, professional shows and exhibits, symposia, medical education and support of health economics and outcomes research.

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 48%, 43% and 42% of our total revenue for the years ended December 31, 2014, 2013 and 2012, respectively. We had sales to three

distributors for whom sales exceeded 10% of total revenue for the year ended December 31, 2014. These distributors were Cardinal Healthcare Corporation, McKesson/PSS Corporation and Fisher Scientific.

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 sites include our facilities 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, California facility are packaged and shipped by a local third party.

Our Athens facility consists of clean rooms (FS-209E Class 1000: ISO Class 6) for the culturing and dispensing of cell cultures under cGMP conditions. The facility also has laboratories devoted to tissue culture for the production of monoclonal antibodies. 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. In 2013, we added a molecular manufacturing laboratory dedicated to the manufacture and assembly of our molecular products.

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 (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.

9

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 FDA approval has been obtained. 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”) and Japan. EU Regulations and Directives generally classify health care products either as medicinal products, medical devices or in vitro diagnostics. The CE Mark certification 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. The Japanese regulations require registration of in vitro diagnostic products with the Japanese Ministry of Health, Labor and Welfare. Additional clinical trials are typically required for registration purposes. For products marketed in Canada, 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 2030 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 contracting party 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 the effective distribution, advertising, promotion and brand name recognition of the marketer. 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, who are in great demand. 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 (“Beckman”), Fisher Scientific Corporation (“Fisher”), Becton Dickinson and Company (“Becton”), Meridian Bioscience, Inc. (“Meridian”) and Chemicon International, Inc. (“Chemicon”). 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 of infectious diseases in which we currently have relevant market share.

Human Resources

As of December 31, 2014, we had 610 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, 2014 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, 57, 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 25 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, 60, 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.

Robert J. Bujarski, J.D., 46, 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.

Mark W. Smits, 57, has served as Senior Vice President of Commercial Operations since May 2011. From August 2010 to May 2011, Mr. Smits served as Vice President of Sales and Marketing for Neogenomics, a provider of cancer-focused testing laboratories. From October 2008 to August 2010, Mr. Smits was Vice President of Marketing and Business Development for Fisher HealthCare, Inc., a division of Thermo Fisher Scientific, Inc. which is a supplier of analytical instruments, laboratory equipment, software, services, consumables and reagents. Mr. Smits led the sourcing and business development efforts for Fisher HealthCare. Prior to Fisher HealthCare, Mr. Smits spent 25 years with Abbott Diagnostics, which offers instrument systems and tests for hospitals, reference labs, blood banks, physician offices, and clinics, serving in several different roles including, from October 2002 until September 2008, Divisional Vice President, Western United States Commercial Operations, where he led an organization of 250 people to provide sales, service and support to customers. Mr. Smits received his B.S. from Texas A&M University.

John D. Tamerius, Ph.D., 69, has been our Senior Vice President, Clinical/Regulatory Affairs since November 2008. Dr. Tamerius previously served as the Company's Vice President, Clinical/Regulatory Affairs from 2005 to November 2008. Dr. Tamerius has held a variety of positions with us including, among others: Vice President for Research and Development and General Manager of the Company's Specialty Products Group. Dr. Tamerius joined the Company in 1983 with the acquisition of Cytotech, Inc. where he served as President. Dr. Tamerius was previously a research associate at Scripps Clinic and Research Foundation. Dr. Tamerius performed postdoctoral research in tumor immunology at the Fred Hutchinson Cancer Center in Seattle and was awarded a Bachelor of Science, Master of Science, and Doctor of Philosophy in Microbiology and Immunology, all from the University of Washington.

Werner Kroll, Ph.D., 58, 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.

Item 1A. Risk Factors

Risks Related to Our Business

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. For the year ended December 31, 2014, total revenue increased 4% to $182.6 million compared to the year ended December 31, 2013. The increase in total revenues was primarily due to an increase in influenza product sales. For further discussion of this increase, refer to Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operation" included in this Annual Report.

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 e

xpectations. 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:

- 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;
- timing of the onset, length and severity of the cold and flu seasons;
- 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 of our products;
- changes in the reimbursement systems or reimbursement amounts that end-users 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 health care 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 2030. 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 require 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 increased operating expenses as a result of our increased 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 and our working capital line of credit and the sale of 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 for approximately 48%, 43%, and 42% of our total revenue for the years ended December 31, 2014, 2013 and 2012, respectively.

We had sales to three distributors for whom sales exceeded 10% of total revenue for the year ended December 31, 2014. 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 were 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.

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 in 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 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, 2014, 2013 and 2012, sales of our infectious disease products (including influenza test sales) accounted for 71%, 73%, and 71% respectively, of total revenue.

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 is likely to 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. For example, we have recently completed two business acquisitions. In 2013, we acquired BioHelix and AnDiaTec (collectively, the "recent acquisitions"). We expect to need to execute a number of tasks in a timely, efficient and successful manner in order to realize the benefits and cost savings of the recent acquisitions, including retaining and assimilating key personnel, managing the regulatory and reimbursement approval processes, intellectual property protection strategies and commercialization activities, creating uniform standards, controls, procedures, policies and information systems, including with respect to disclosure controls and procedures and internal control over financial reporting, and meeting the challenges inherent in efficiently managing an increased number of employees potentially in different geographic locations, including the need to implement appropriate systems, policies, benefits and compliance programs. The recent acquisitions or other acquisitions may subject us to other risks, including unanticipated costs and expenditures, changes in the business, currency risks, potential changes in relationships with strategic partners, potential contractual or intellectual property issues, fluctuations in quarterly results and financial condition as a result of timing of acquisitions and potential accounting charges and write-downs, and potential unknown liabilities associated with the strategic combination and the combined operations. 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 attorney 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 $8.9 million, $9.0 million and $9.4 million for the years ended December 31, 2014, 2013 and 2012, 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.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt.

Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including cash due upon conversion of our Convertible Senior Notes ("Convertible Senior Notes"), 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 our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as 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.

We may not have the ability to raise the funds necessary to settle conversions of our Convertible Senior Notes or purchase the Convertible Senior Notes as required upon a fundamental change, and our existing debt contains, and our 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. Certain fundamental changes and the exercise of any repurchase right of Convertible Senior Note holders upon a fundamental change would result in an event of default under our existing Senior Credit Facility. A fundamental change may also constitute an event of default or prepayment under, and result in the acceleration of the maturity of, our other then-existing indebtedness. 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. In addition, restrictions in our current or then existing credit facilities or other indebtedness, if any, may not allow us to purchase the Convertible Senior Notes upon a fundamental change or make cash payments upon conversions of the Convertible Senior Notes (including, as noted above, restrictions in our existing Senior Credit Facility on the repurchase of Convertible Senior Notes upon a fundamental change). 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 indebtedness, if any. 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.

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.

Our Senior Credit Facility imposes restrictions on our operations and activities, limits the amount we can borrow, and requires us to comply with various financial covenants.

On August 10, 2012, we entered into an amended and restated $140.0 million senior secured syndicated credit facility, as amended (the “Senior Credit Facility”), which matures on August 10, 2017. The agreement governing the Senior Credit Facility is subject to certain customary covenants, including among others: limitation on liens; limitation on

mergers, consolidations and sales of assets; limitation on debt; limitation on dividends, stock redemptions and the redemption and/or prepayment of other debt; limitation on investments (including loans and advances) and acquisitions; limitation on transactions with affiliates; and limitation on disposition of assets. We are also subject to financial covenants which include a funded debt to adjusted earnings before interest, taxes, depreciation and amortization, and stock-based compensation ("adjusted EBITDA") ratio (as defined in the Senior Credit Facility) and an interest coverage ratio. The Senior Credit Facility is secured by substantially all of our

present and future assets and properties. If we fail to comply with these covenants, our Senior Credit Facility could become due and payable prior to maturity. As of December 31, 2014, we were in compliance with all financial covenants.

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 or cause us to fail to comply with financial covenants in the documents governing our indebtedness. As a result, we may not be able to draw on our Senior Credit Facility and we may need to seek to raise funds through public or private debt or sale of equity to achieve our business strategy or to avoid non-compliance with our financial covenants. 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.

Volatility and disruption to the global capital and credit markets may adversely affect our results of operations and financial condition, as well as our ability to access credit and the financial soundness of our customers and suppliers.

The global capital and credit markets have historically experienced a period of unprecedented turmoil and upheaval, characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. federal government. If these conditions recur, it could adversely affect the demand for our products and services and, therefore, reduce purchases by our customers, which would negatively affect our results of operations and financial condition. In addition, interest rate fluctuations, financial market volatility or credit market disruptions may limit our access to capital, and may also negatively affect our customers' and our suppliers' ability to obtain credit to finance their businesses. As a result, our customers' needs and ability to purchase our products or services may decrease, and our suppliers may increase their prices, reduce their output or change their terms of sale. 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 health care 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 proposed reclassifications of rapid influenza detection devices from Class I to Class II devices. If such reclassifications affected 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 in the U.S. Although we cannot fully predict the many ways that health care reform might affect our business, the law imposes a 2.3% medical device excise tax 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 years ended December 31, 2014 and 2013, we incurred $2.0 million and $1.8 million related to the medical device tax, respectively. It is unclear whether and to what extent, if at all, other anticipated developments resulting from health care reform, such as an increase in the number of people with health insurance, may provide us additional revenue to offset this increased tax. If additional revenue does not materialize, or if our efforts to offset the excise tax through spending cuts or other actions are unsuccessful, the increased tax burden will adversely affect our financial performance.

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 t

he 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 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 sizeable 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 health care 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 components could adversely affect our operations and financial results.

Some of our raw materials 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 and 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 and components, and 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 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 or from some other matter, that claim could have a material adverse effect on our results of operations.

We manage our businesses utilizing complex computer systems that require regular maintenance and upgrades; an interruption to these systems could disrupt our business or force us to expend excessive costs.

We utilize complex computer systems, including enterprise resource planning and warehouse management systems, to support our business units. Regular upgrades of our computer hardware and software revisions are necessary. We cannot assure that our systems will meet our future business needs or that upgrades will operate as designed. We cannot assure that there will not be associated excessive costs or disruptions in portions of our business in the course of our maintenance, support and/or upgrade of these systems. In particular, any disruptions, delays or deficiencies in the implementation of our new 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.

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.

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 13%, 13%, and 14% of our total revenue for the years ended December 31, 2014, 2013 and 2012, 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;
- 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.

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, subject to the restrictions contained in our debt instruments.

As of December 31, 2014, we had $95.7 million available to borrow under the Senior Credit Facility. Our ability to borrow under the Senior Credit Facility fluctuates from time to time due to, among other factors, our borrowings under the facility and its funded debt to adjusted EBITDA ratio as and when measured under the Senior Credit Facility. As of December 31, 2014, there were no borrowings outstanding under the Senior Credit Facility.

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.

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.

In addition, 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 of our results of operations 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.

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. Our Senior Credit Facility contains restrictions prohibiting us from paying any cash dividends without the lenders' prior approval. If we do not pay cash dividends, a return on one's investment may only occur if our common stock price rises above the price at which it was purchased.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

At December 31, 2014, 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	2019 - options to extend for three additional 5 year periods	78,000	Administrative offices, sales and marketing, 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	2017 - options to extend for two additional 5 year periods	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 the 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, 2014	$23.75	$28.68
September 30, 2014	$21.02	$26.99
June 30, 2014	$20.67	$27.54
March 31, 2014	$27.30	$31.71
December 31, 2013	$24.00	$30.89
September 30, 2013	$25.34	$29.42
June 30, 2013	$20.40	$25.99
March 31, 2013	$19.87	$24.62

As of February 19, 2015, we had approximately 428 common stockholders of record. No cash dividends were declared for our common stock during the fiscal years ended in 2014 or 2013, and we do not anticipate paying any dividends in the foreseeable future. Our Senior Credit Facility contains restrictions on the payment of cash dividends. See Note 2 in the Notes to Consolidated Financial Statements included in this Annual Report.

Stock Repurchases

The Company did not make any stock repurchases during the year ended December 31, 2014, and there was $50.0 million available under the Company's share repurchase program. During the year ended December 31, 2014, 68,368 shares of outstanding common stock with a value of $2.0 million were repurchased in connection with payment of minimum tax withholding obligations for certain employees relating to the lapse of restrictions on certain restricted stock awards. These shares are not considered repurchases under the Company’s repurchase program.

The table below sets forth information regarding repurchases of our common stock by us during the three months ended December 31, 2014:

Period	Total number of shares purchased	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 (1)
October	—	—	—	50,000,000
November	—	—	—	50,000,000
December	—	—	—	50,000,000
Total	—	—	—	50,000,000

(1) On April 23, 2013, we announced that our Board of Directors authorized us 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. The repurchase program will expire on April 22, 2015 unless extended by our Board of Directors.

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 Pharmaceutical Index, Nasdaq Health Care Index, and Nasdaq Medical Supplies Index for the period beginning December 31, 2009 and ending December 31, 2014. In our previous Form 10-K we utilized the Nasdaq Pharmaceutical Index as the industry index for comparison. In our performance graph for the year ended 2014, we added two new indices, the Nasdaq US Benchmark Medical Supplies Index and the Nasdaq Health Care Index (IXHC), which will replace our comparison to the Nasdaq Pharmaceutical Index in future periods. We believe that the new indices provide for greater comparability as they contain more competitors and are further aligned with our business. Total return comparisons for both the prior index and new indices are included in the performance graph below. The graph assumes an initial investment of $100 on December 31, 2009 in our common stock, the Nasdaq Composite Index, the Nasdaq Pharmaceutical Index, the Nasdaq 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 Pharmaceutical, NASDAQ Medical Supplies and NASDAQ Health Care Indices

Company/Index	Base Period 12/31/2009	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014
Quidel Corporation	$100.00	$104.86	$109.80	$135.49	$224.17	$209.87
NASDAQ Composite	$100.00	$116.91	$114.81	$133.07	$184.06	$208.71
NASDAQ Pharmaceutical	$100.00	$98.97	$113.53	$125.58	$165.64	$196.93
NASDAQ Medical Supplies	$100.00	$105.94	$101.55	$123.28	$148.99	$176.88
NASDAQ Health Care	$100.00	$110.33	$115.31	$146.72	$230.41	$296.01

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,				
	2014	2013(1)	2012	2011	2010(2)
	(in thousands, except per share data)				
Total revenues	$182,615	$175,410	$155,741	$158,603	$113,339
Costs and expenses					
Cost of sales (excludes amortization of intangible assets)(3)	74,180	66,976	61,285	62,865	51,489
Amortization of inventory fair value adjustment from acquisition	—	—	—	—	1,118
Total cost of sales (excludes amortization of intangible assets) (3)	74,180	66,976	61,285	62,865	52,607
Research and development	37,913	34,186	27,716	26,325	23,696
Sales and marketing	41,533	33,829	30,319	25,751	23,972
General and administrative	25,811	25,581	19,800	21,989	18,802
Amortization of intangible assets from acquired businesses and technology	8,828	8,171	6,935	7,124	6,731
Impairment loss	3,558	—	—	—	—
Facility restructuring charges and business acquisition and integration costs	—	1,825	—	—	2,276
Total costs and expenses	191,823	170,568	146,055	144,054	128,084
Operating (loss) income	(9,208)	4,842	9,686	14,549	(14,745)
Interest expense, net (4)	(1,775)	(1,408)	(2,075)	(3,065)	(2,675)
(Loss) income before (benefit) provision for taxes	(10,983)	3,434	7,611	11,484	(17,420)
(Benefit) provision for income taxes	(3,909)	(3,956)	2,618	3,851	(6,149)
Net (loss) income	$(7,074)	$7,390	$4,993	$7,633	$(11,271)
Basic earnings (loss) per share	$(0.21)	$0.22	$0.15	$0.23	$(0.39)
Diluted earnings (loss) per share	$(0.21)	$0.21	$0.15	$0.23	$(0.39)
Shares used in basic per share calculation	34,451	33,836	33,068	32,903	28,582
Shares used in diluted per share calculation	34,451	34,947	33,702	33,320	28,582

Balance Sheet Data

	December 31, 2014	2013	2012	2011	2010
	(in thousands)				
Cash and cash equivalents	$200,895	$8,388	$14,856	$61,332	$6,788
Working capital	$238,736	$54,610	$52,271	$71,452	$40,250
Total assets	$451,550	$271,485	$242,099	$278,894	$214,593
Long-term debt and lease obligation, net of current portion	$146,714	$5,126	$10,567	$47,947	$79,774
Stockholders' equity	$245,011	$223,779	$199,780	$185,386	$112,521
Common shares outstanding	34,433	34,073	33,451	33,276	28,514

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

(2) Includes the results of operations of DHI from its date of acquisition, February 19, 2010.

(3) Excludes amortization of intangible assets of $6,283, $6,079, $5,753, $6,667 and $5,852 for the years ended December 31, 2014, 2013, 2012, 2011 and 2010, respectively.

(4) Includes reclassification of $677, $840, $809 and $544 from general and administrative expense for the years ended December 31, 2013, December 31, 2012, December 31, 2011 and December 31, 2010, 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 primarily include applications in infectious diseases, women's health and gastrointestinal diseases. 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 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.

A majority of our total revenues relate to three product families. For the years ended December 31, 2014, 2013 and 2012, we derived approximately 69%, 59% and 58%, 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 48%, 43% and 42% of our total revenue for the years ended December 31, 2014, 2013 and 2012, respectively, were related to sales through our three largest distributors.

For the year ended December 31, 2014, total revenue increased 4% to $182.6 million as compared to the year ended December 31, 2013. The increase in total revenues was primarily due to an increase in influenza product sales.

Our primary objective is to increase shareholder value by building a broader-based diagnostic company capable of delivering revenue growth and more 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 varying 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 three parts:

- rapid point of care immunoassay tests for use in physician offices, hospital laboratories and emergency departments, retail clinics, and other urgent care settings;
- direct fluorescent assays ("DFA") and culture-based tests for the clinical virology laboratory; and
- molecular diagnostic tests across a number of laboratory segments.

Our strategy to accomplish our primary objective includes the following:

- leveraging our current infrastructure to develop and launch rapid immunoassays, such as additional assays for our FDA approved Sofia® Analyzer;
- developing a molecular diagnostics franchise that incorporates distinct testing platforms, AmpliVue®, Savanna™ and Solana™ and that leverages our molecular assay development competencies; and
- strengthening our position with distribution partners and our 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 to address unmet clinical needs, and
- pursuit of collaborations with 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;
- continue to focus on strengthening our market and brand leadership in infectious diseases and women's health 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;
- 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 effort to create a 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.

Outlook

We expect revenue growth over the next 12 months and a related positive impact on gross margin and earnings. 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 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, 2014 and 2013

Total Revenues

The following table compares total revenues for the years ended December 31, 2014 and 2013 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)		
	2014	2013	$	%	
Infectious disease net product sales	$130,416	$128,079	$2,337	2	%
Women’s health net product sales	34,332	33,328	1,004	3	%
Gastrointestinal disease net product sales	7,414	6,622	792	12	%
Other net product sales	2,772	3,464	(692)	(20)	%
Royalty, license fees and grant revenue	7,681	3,917	3,764	96	%
Total revenues	$182,615	$175,410	$7,205	4	%

For the year ended December 31, 2014, total revenue increased 4% to $182.6 million. The increase in total revenues was primarily due to an increase in sales of influenza, Strep A, and RSV products driven by gains made on the Sofia platform. Gains in the women's health segment were driven by increased sales of our Thyretain product for diagnosis of Grave's Disease. Gains in the gastrointestinal disease segment were driven primarily by increased adoption of the AmpliVue C. difficile assay. The revenue from our royalty, license fees and grant revenue category for all periods relates to grant revenues associated with the Bill and Melinda Gates Foundation grant agreement and research and development activities for our Savanna HIV viral load assay and system in development as well as royalty payments earned on our patented technologies utilized by third parties. See further discussion in Note 1 in the Notes to the Consolidated Financial Statements included in this Annual Report.

Cost of Sales

Cost of sales increased to 41% of total revenues, for the year ended December 31, 2014 compared to 38% of total revenues, for the year ended December 31, 2013. The absolute dollar increase in cost of sales of $7.2 million for the year ended December 31, 2014 from the year ended December 31, 2013 is primarily related to the variable nature of direct costs (material and labor) associated with the 4% increase in total revenues in 2014 combined with the increased cost of depreciation on a larger installed base of Sofia instruments in 2014 and higher excess and obsolete inventory expense. The increase in cost of sales as a percentage of total revenue is driven by the same factors, as well as, product mix.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2014 and 2013 (in thousands, except percentages):

	For the year ended December 31,								
	2014			2013					
	Operating expenses	As a % of total revenues		Operating expenses	As a % of total revenues		Increase (decrease) $	%	
Research and development	$37,913	21	%	$34,186	19	%	$3,727	11	%
Sales and marketing	$41,533	23	%	$33,829	19	%	$7,704	23	%
General and administrative	$25,811	14	%	$25,581	15	%	$230	1	%
Amortization of intangible assets from acquired businesses and technology	$8,828	5	%	$8,171	5	%	$657	8	%
Impairment loss	$3,558	2	%	$—	—	%	$3,558	N/A	
Facility restructuring charge	$—	—	%	$1,825	1	%	$(1,825)	N/A	

Research and Development Expense

Research and development expense for the year ended December 31, 2014 increased from $34.2 million to $37.9 million primarily due to a $4.9 million increase in spend on our molecular platforms. Also contributing to the increase was a reduction in reimbursement for research and development costs associated with a third-party collaboration agreement of $1.0 million in 2014 as more fully described in Note 1 in the Notes to the Consolidated Financial Statements included in this Annual Report. This is partially offset by reductions in spend for other areas of development.

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, 2014 increased from $33.8 million to $41.5 million driven primarily by additional investment in our sales organization through expansion and training of a larger sales force in 2014 relative to 2013.

General and Administrative Expense

General and administrative expense for the year ended December 31, 2014 increased from $25.6 million to $25.8 million. General and administrative expenses include the 2.3% medical device excise tax, personnel costs, business development activities, and other general expenses.

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 the Project Stella (Bobcat) assets and related technology. As a result, we recorded an impairment loss totaling $3.6 million in the third quarter of 2014. See further discussion in Note 10 in the Notes to the Consolidated Financial Statements.

Facility Restructuring Charge

In 2013, we relocated our Santa Clara, California manufacturing operations to our facility in Athens, Ohio. In connection with the relocation, restructuring expense amounted to $1.8 million for the year ended December 31, 2013, which included employee termination benefits and impairment charges related to the facility lease. We had no restructuring expenses for the year ended December 31, 2014.

Interest Expense, Net

Interest expense primarily relates to interest paid on borrowings under the Senior Credit Facility, interest paid on our lease obligation associated with our San Diego McKellar facility, and 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. The increase in interest expense of $0.4 million for the year ended December 31, 2014 was due to the interest expense related to the Convertible Senior Notes. There were no borrowings under the Senior Credit Facility during the year ended December 31, 2014.

Income Taxes

We recognized an income tax benefit of $3.9 million and $4.0 million for the years ended December 31, 2014 and 2013, respectively. During 2014, the Company recorded a valuation allowance for deferred tax assets of $2.3 million, which was offset by the federal and state research and development credits of $0.8 million and release of tax reserves and related interest of approximately $1.0 million related to the expiration of the statute of limitations on assessment for certain state matters. During 2013, we were notified by the Internal Revenue Service that the Congressional Joint Committee of Taxation had completed its review of and proposed no changes to our tax returns filed for the tax periods 2008 through 2010. As a result, we released tax reserves and related interest of approximately $3.5 million in 2013. On January 3, 2013, the American Taxpayer Relief Act of 2012 was signed into law reinstating the federal research and development credit for the 2012 and 2013 years. Accordingly, we recorded the benefit related to the 2012 federal research and development credit of approximately $0.5 million during the year ended December 31, 2013.

Comparison of years ended December 31, 2013 and 2012

Total Revenues

The following table compares total revenues for the years ended December 31, 2013 and 2012 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)		
	2013	2012	$	%	
Infectious disease net product sales	$128,079	$110,982	$17,097	15	%
Women’s health net product sales	33,328	32,653	675	2	%
Gastrointestinal disease net product sales	6,622	6,328	294	5	%
Other net product sales	3,464	3,326	138	4	%
Royalty, license fees and grant revenue	3,917	2,452	1,465	60	%
Total revenues	$175,410	$155,741	$19,669	13	%

For the year ended December 31, 2013, total revenue increased 13% to $175.4 million from $155.7 million for the year ended December 31, 2012. The increase in total revenues was primarily due to an increase in influenza product sales. The revenue from our royalty, license fees and grant revenue category for all periods primarily relate to royalty payments earned on our patented technologies utilized by third parties and revenue from grants for research and development activities.

Cost of Sales

Cost of sales decreased to 38% of total revenues, for the year ended December 31, 2013 compared to 39% of total revenues, for the year ended December 31, 2012. The absolute dollar increase in cost of sales of $5.7 million for the year ended

December 31, 2013 from the year ended December 31, 2012 is primarily related to the variable nature of direct costs (material and labor) associated with the 13% increase in total revenues in 2013. The decrease in cost of sales as a percentage of total revenue was primarily due to a more favorable product mix in 2013 related to our higher margin influenza products, partially offset by an increase in depreciation of leased Sofia instruments in 2013.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2013 and 2012 (in thousands, except percentages):

	For the year ended December 31,								
	2013			2012					
	Operating expenses	As a % of total revenues		Operating expenses	As a % of total revenues		Increase (decrease) $	Increase (decrease) %	
Research and development	$34,186	19	%	$27,716	18	%	$6,470	23	%
Sales and marketing	$33,829	19	%	$30,319	19	%	$3,510	12	%
General and administrative	$25,581	15	%	$19,800	13	%	$5,781	29	%
Amortization of intangible assets from acquired businesses and technology	$8,171	5	%	$6,935	4	%	$1,236	18	%
Facility restructuring charge	$1,825	1	%	$—	—	%	$1,825	N/A	

Research and Development Expense

Research and development expense for the year ended December 31, 2013 increased from $27.7 million to $34.2 million due to planned increases in our development of molecular technologies, primarily on our Savanna program. In addition, there were increases related to the acquisition of both Biohelix and AnDiaTec totaling $1.2 million. Also contributing to the increase was a reduction in reimbursement for research and development costs of $1.4 million and $3.0 million for the years ended December 31, 2013 and 2012, respectively, associated with a third-party collaboration agreement as more fully described in Note 1 in the Notes to the Consolidated Financial Statements included in this Annual Report.

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, 2013 increased from $30.3 million to $33.8 million primarily due to additional investments of $2.4 million in our sales organization including an increase in personnel, travel, training costs, and incentives related to commercialization of new products. Other key components of this expense relate to continued investment in assessing future product extensions and enhancements and market research.

General and Administrative Expense

General and administrative expense for the year ended December 31, 2013 increased from $19.8 million to $25.6 million primarily related to the 2.3% medical device excise tax of $1.8 million, acquisition related expenses of $1.0 million, an increase in stock compensation expense of $0.9 million related to the modification of performance awards and $0.7 million related to our enterprise resource planning system upgrade.

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. Amortization of intangible assets from acquired technology consists primarily of expense associated with purchased technology.

Facility Restructuring Charge

In 2013, we relocated our Santa Clara, California manufacturing operations to our facility in Athens, Ohio. In connection with the relocation, restructuring expense amounted to $1.8 million for the year ended December 31, 2013, which included employee termination benefits and impairment charges related to the facility lease.

Interest Expense, Net

Interest expense primarily relates to interest paid on borrowings under the Senior Credit Facility and interest paid on our lease obligation associated with our San Diego facility. The decrease in interest expense of $0.7 million for the year ended December 31, 2013 was largely due to no borrowings under the Senior Credit Facility throughout most of the year ended December 31, 2013.

Income Taxes

We recognized an income tax benefit of $4.0 million and income tax expense of $2.6 million for the years ended December 31, 2013 and 2012, respectively. During 2013, we were notified by the Internal Revenue Service that the Congressional Joint Committee of Taxation had completed its review of and proposed no changes to our tax returns filed for the tax periods 2008 through 2010. As a result, we released tax reserves and related interest of approximately $3.5 million. On January 3, 2013, the American Taxpayer Relief Act of 2012 was signed into law reinstating the federal research and development credit for the 2012 and 2013 years. Accordingly, we recorded the benefit related to the 2012 federal research and development credit of approximately $0.5 million during the year ended December 31, 2013.

Liquidity and Capital Resources

As of December 31, 2014 and 2013, our principal sources of liquidity consisted of the following (in thousands):

	December 31,	
	2014	2013
Cash and cash equivalents	$200,895	$8,388
Restricted cash	3,127	969
Cash, cash equivalents, and restricted cash	$204,022	$9,357
Working capital including cash, cash equivalents, and restricted cash	$238,736	$54,610
Amount available to borrow under the Senior Credit Facility	$95,700	$140,000

As of December 31, 2014, we had $200.9 million in cash and cash equivalents, which is primarily attributable to the issuance of Convertible Senior Notes for an aggregate principal amount of $172.5 million in December 2014. During the year ended December 31, 2014, the Company received $10.6 million, pursuant to a grant agreement, which was restricted as to use until expenditures contemplated in the grant were incurred or committed. The Company recorded this restricted cash as a current asset as the Company anticipates making expenditures under the grant within one year. As of December 31, 2014, restricted cash was $3.1 million.

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 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 was offset by extended payables terms, resulting in an increase of $4.4 million and reduced inventories of $2.9 million.

Cash provided by operating activities was $25.7 million during the year ended December 31, 2013. The Company had net income of $7.4 million, including non-cash charges of $24.7 million of depreciation and amortization of intangible assets and pr

37

operty and equipment, and stock-based compensation of $8.8 million. The most significant changes in operating assets and liabilities in 2013 was an increase in inventories of $12.0 million due to planned increases related to our molecular products, our SPG facility relocation and the seasonal nature of our influenza business.

Cash provided by operating activities was $19.6 million during the year ended December 31, 2012. The Company had net income of $5.0 million, including non-cash charges of $23.3 million of depreciation and amortization of intangible assets and property and equipment, and stock-based compensation of $6.6 million. The most significant changes in operating assets and liabilities in 2012 included an increase in accounts receivable of $17.9 million related to an early start to the 2012/2013 cold and flu season in the fourth quarter of 2012.

Our investing activities used $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. Our investing activities used $9.2 million and $2.3 million of net cash during the year ended December 31, 2013 for the acquisitions of BioHelix and AnDiaTec, respectively. Our investing activities used $28.6 million during the year ended December 31, 2012 to exercise a buyout clause under the Alere license agreement. During the year ended December 31, 2012, the Company exercised the buy-out right under the Alere Amendment, which allowed us to buy-out any remaining future royalty obligation for a fixed cash payment in the amount of $15.6 million less $1.0 million of specified third quarter 2011 royalties. In addition, the Company used $12.2 million of cash for investing activities associated with the acquisition of production and scientific equipment, and building improvements during the year ended December 31, 2012.

We are currently planning approximately $15.0 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 cash flow from operations and other available sources of liquidity. We have $3.4 million in firm purchase commitments with respect to such planned capital expenditures as of December 31, 2014.

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. Our financing activities provided $1.8 million of cash during the year ended December 31, 2013 primarily related to proceeds from the issuance of common stock through exercise of options of $7.9 million, partially offset by repayments under our Senior Credit Facility of $5.0 million. Our financing activities used approximately $37.5 million of cash during the year ended December 31, 2012. This was primarily related to repayments under our Senior Credit Facility and other debt payments of $38.5 million, and repurchases of our common stock of $2.9 million which was partially offset by proceeds from the issuance of common stock through exercise of options of $4.7 million.

On August 10, 2012, we entered into an amended and restated $140.0 million Senior Credit Facility, which matures on August 10, 2017. The Senior Credit Facility amended and restated our $120.0 million senior secured credit facility dated October 8, 2008. As part of this amendment, we incurred an additional $1.0 million in deferred financing costs related to the Senior Credit Facility. We had previously recorded $0.6 million related to our prior credit facility. As of December 31, 2014 the Company had deferred financing costs related to the Senior Credit Facility of $0.5 million included as a portion of other non-current assets and $0.3 million included as a portion of prepaid expenses and other current assets. The Senior Credit Facility bears interest at either LIBOR or the base rate, plus, in each case, an applicable margin. The base rate is equal to the highest of (i) the lender’s prime rate, (ii) the federal funds rate plus one-half of one percent and (iii) LIBOR plus one percent. The applicable margin is generally determined in accordance with a performance pricing grid based on our leverage ratio and ranges from 1.25% to 2.50% for LIBOR rate loans and from 0.25% to 1.50% for base rate loans. The agreement governing the Senior Credit Facility is subject to certain customary limitations, including among others: limitation on liens; limitation on mergers, consolidations and dispositions of assets; limitation on debt; limitation on dividends, stock redemptions and the redemption and/or prepayment of other debt; limitation on investments (including loans and advances) and acquisitions; and limitation on transactions with affiliates. We are also subject to financial covenants which include a funded debt to adjusted EBITDA ratio (as defined in the Senior Credit Facility) not to exceed 3:1 as of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:1 as of the end of each fiscal quarter. The Senior Credit Facility is secured by substantially all of our present and future domestic assets and properties. Our ability to borrow under the Senior Credit

Facility fluctuates from time to time due to, among other factors, our borrowings under the facility and our funded debt to adjusted EBITDA ratio. As of December 31, 2014, the Company had no borrowings outstanding and had $95.7 million available to borrow under the Senior Credit Facility. As of December 31, 2014, the Company was in compliance with all financial covenants.

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 line, 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. Based on our current cash position and our current assessment of future operating results, we believe that our existing sources of liquidity will be adequate to meet our operating needs during the next 12 months.

Off-Balance Sheet Arrangements

At December 31, 2014 and 2013, 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, 2014, 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)	$206,136	$5,606	$11,212	$11,212	$178,106
Lease obligation (2)	6,781	1,134	2,297	2,332	1,018
Operating lease obligations (3)	12,742	1,794	4,143	3,291	3,514
Non-cancellable purchase commitments (4)	3,360	3,192	168	—	—
Total contractual obligations	$229,019	$11,726	$17,820	$16,835	$182,638

(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, 2014. The facility is subject to a financing arrangement with payments through December 2019. 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, 2014. 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 2011, we exercised our renewal option for the Athens, Ohio location. The amended lease expires in 2017 with two options to extend the lease for additional five-year periods through 2027. Future minimum lease payments are included in the table above.

(4) Reflects our $3.4 million of non-cancellable commitments to purchase property, plant and equipment and inventory 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 $8.9 million, $9.0 million and $9.4 million for the years ended December 31, 2014, 2013 and 2012, respectively including $8.0 million, $8.0 million and $8.4 million in amortization expense for 2014, 2013 and 2012, 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, 2014, we had approximately $0.8 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 $5.8 million in potential contingent consideration payments related to achievement of certain revenue targets under acquisition agreements. In addition to revenue targets under the AnDiaTec acquisition agreement, there are also contingent payments remaining of up to $2.2 million upon achievement of certain research and development mile

39

stones as of December 31, 2014. 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. The table also excludes $0.5 million related to a research and development target achieved as of December 31, 2014, which is included in accrued payroll and related expenses as of December 31, 2014. See Note 6 in the Notes to the Consolidated Financial Statements included in this Annual Report for further discussion of our contingent consideration.

New Accounting Standards

In May 2014, the FASB issued guidance codified in ASC Topic 606, Revenue Recognition - Revenue from Contracts with Customers, which amends the guidance in former ASC Topic 605, Revenue Recognition. This guidance is intended to improve and converge with international standards the financial reporting requirements for revenue from contracts with customers. 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 guidance is effective for annual reporting periods beginning after December 15, 2016, with early adoption prohibited. The Company is currently evaluating the impact of this guidance and expects to adopt the standard in the first quarter of 2017.

In August 2014, the FASB issued guidance codified in ASU 2014-15 (Subtopic 205-40), Presentation of FinancialStatements - Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The guidance requiresmanagement 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 have to 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 is currently evaluating the impact of this guidance and expects to adopt the standard for the annual reporting period ended December 31, 2016.

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 which 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 shorter of the lease term or 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 also earns income from the licensing of technology.

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 and expects to receive the remaining milestone payments of up to $2.4 million in 2015 and $2.8 million in 2016. The Company recognizes grant revenue on 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, 2014, 2013 and 2012, we recognized $6.3 million, $2.6 million and $0.5 million as grant revenue, respectively. The Company classified $3.1 million and $1.0 million of funds received from the Bill and Melinda Gates Foundation as restricted cash as of December 31, 2014 and December 31, 2013, respectively. In addition, the Company has classified $6.3 million and $2.0 million as deferred grant revenue as of December 31, 2014 and December 31, 2013, respectively.

Stock-Based Compensation

Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option award. 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. Compensation expense for time-based restricted stock awards and units is 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 is tied to achievement of specific Company goals in 2014 and 2013. For purposes of measuring compensation expense, we estimate the amount of shares ultimately expected to vest at each reporting date based on management's expectations regarding achievement of 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. This may result in significant expense recognition in the period in which the performance goals are met or when achievement of the goals is deemed probable or may result in the reversal of previously recognized stock-based compensation expense if the performance criteria are deemed not probable of being met. 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.

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.

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 market on a part-by-part basis. This policy requires us to make estimates regarding the market value of our inventories, including an assessment of excess or obsolete inventories. 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, 2014 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. 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 is required. A significant piece of objective negative evidence evaluated was that the cumulative before-tax results incurred over the three-year period ended December 31, 2014 were slightly profitable. Based upon the available evidence as of December 31, 2014, we were not able to conclude it is more likely than not certain deferred tax assets will be realized. Therefore, we recorded a valuation allowance of $2.3 million against our deferred tax assets. 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, 2014 and 2013, deferred tax assets do not include $1.5 million and $1.0 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. Additional paid-in capital would be increased up to $1.5 million if such excess tax benefits are realized.

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 had no borrowings outstanding under our Senior Credit Facility at December 31, 2014. If we had borrowings under our Senior Credit Facility the interest rate would have been 1.41% as of December 31, 2014. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not increase our annual interest expense as there are no borrowings.

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, 2014, our cash and cash equivalents were placed in certificates of deposit, money market or overnight funds that we believe are highly liquid and not subject to material market fluctuation risk.

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 a supply agreement with a foreign vendor whereby we evenly share the foreign currency exchange fluctuation risk. We may, in the future, enter into similar such arrangements.

Item 8. Financial Statements and Supplementary Data

Table of Contents

Report of Independent Registered Public Accounting Firm	46
Consolidated Balance Sheets as of December 31, 2014 and 2013	47
Consolidated Statements of Operations for the years ended December 31, 2014, 2013 and 2012	48
Consolidated Statements of Comprehensive (Loss) Income for the years ended December 31, 2014, 2013 and 2012	49
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2014, 2013 and 2012	50
Consolidated Statements of Cash Flows for the years ended December 31, 2014, 2013 and 2012	51
Notes to Consolidated Financial Statements	53

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, 2014 and 2013, and the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2014. 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, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, 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, 2014, 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 23, 2015 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Diego, California
February 23, 2015

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

	December 31, 2014	2013
ASSETS		
Current assets:		
Cash and cash equivalents	$200,895	$8,388
Accounts receivable, net	34,466	29,928
Inventories	24,763	27,639
Deferred tax asset—current	8,316	8,362
Restricted cash	3,127	969
Prepaid expenses and other current assets	3,554	3,333
Total current assets	275,121	78,619
Property, plant and equipment, net	49,226	48,057
Goodwill	80,748	80,763
Intangible assets, net	41,890	62,262
Other non-current assets	4,565	1,784
Total assets	$451,550	$271,485
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$12,421	$6,950
Accrued payroll and related expenses	8,349	7,485
Current portion of lease obligation	509	441
Current portion of contingent consideration	733	1,493
Deferred grant revenue	6,330	2,029
Other current liabilities	8,043	5,611
Total current liabilities	36,385	24,009
Long-term debt	142,097	—
Lease obligation, net of current portion	4,617	5,126
Contingent consideration—non-current	5,023	7,315
Deferred tax liability—non-current	14,890	6,318
Income taxes payable	806	2,118
Deferred rent	2,228	1,746
Other non-current liabilities	493	1,074
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, 2014 and 2013	—	—
Common stock, $.001 par value per share; 50,000 shares authorized; 34,433 and 34,073 shares issued and outstanding at December 31, 2014 and 2013, respectively	34	34
Additional paid-in capital	229,374	201,021
Accumulated other comprehensive (loss) income	(29)	18
Retained earnings	15,632	22,706
Total stockholders' equity	245,011	223,779
Total liabilities and stockholders' equity	$451,550	$271,485

See accompanying notes.

47

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

	Year ended December 31,		
	2014	2013	2012
Total revenues	$182,615	$175,410	$155,741
Costs and expenses			
Cost of sales (excludes amortization of intangible assets of $6,283, $6,079, and $5,753, respectively)	74,180	66,976	61,285
Research and development	37,913	34,186	27,716
Sales and marketing	41,533	33,829	30,319
General and administrative	25,811	25,581	19,800
Amortization of intangible assets from acquired businesses and technology	8,828	8,171	6,935
Impairment loss	3,558	—	—
Facility restructuring charges	—	1,825	—
Total costs and expenses	191,823	170,568	146,055
Operating (loss) income	(9,208)	4,842	9,686
Interest expense, net	(1,775)	(1,408)	(2,075)
(Loss) income before (benefit) provision for income taxes	(10,983)	3,434	7,611
(Benefit) provision for income taxes	(3,909)	(3,956)	2,618
Net (loss) income	$(7,074)	$7,390	$4,993
Basic (loss) earnings per share	$(0.21)	$0.22	$0.15
Diluted (loss) earnings per share	$(0.21)	$0.21	$0.15
Shares used in basic per share calculations	34,451	33,836	33,068
Shares used in diluted per share calculations	34,451	34,947	33,702

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(in thousands)

	Year ended December 31,		
	2014	2013	2012
Net (loss) income	$(7,074)	$7,390	$4,993
Other comprehensive (loss) income, net of tax			
Changes in cumulative translation adjustment	(47)	18	—
Comprehensive (loss) income	$(7,121)	$7,408	$4,993

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	Total stockholders' equity
Balance at January 1, 2012	33,276	$33	$175,030	$—	$10,323	$185,386
Issuance of common stock under equity compensation plans	415	—	5,581	—	—	5,581
Cancellation of common stock under equity compensation plans	(9)	—	—	—	—	—
Income tax benefit due to exercise/disposition of employee stock options	—	—	1,102	—	—	1,102
Stock-based compensation expense	—	—	6,125	—	—	6,125
Purchase of common stock	(231)	—	(3,407)	—	—	(3,407)
Net income	—	—	—	—	4,993	4,993
Balance at December 31, 2012	33,451	33	184,431	—	15,316	199,780
Issuance of common stock under equity compensation plans	708	1	8,384	—	—	8,385
Income tax benefit due to exercise/disposition of employee stock options	—	—	2,346	—	—	2,346
Stock-based compensation expense	—	—	8,017	—	—	8,017
Repurchases of common stock	(86)	—	(2,157)	—	—	(2,157)
Changes in cumulative translation adjustment, net of tax	—	—	—	18	—	18
Net income	—	—	—	—	7,390	7,390
Balance at December 31, 2013	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

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year ended December 31,		
	2014	2013	2012
OPERATING ACTIVITIES			
Net (loss) income	$(7,074)	$7,390	$4,993
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation, amortization and other	28,365	24,694	23,261
Stock-based compensation expense	6,724	8,771	6,598
Impairment loss	3,558	—	—
Amortization of debt discount and deferred issuance costs	629	337	146
Loss on disposal of assets	—	202	101
Change in fair value of acquisition contingencies	(910)	80	—
Change in deferred tax assets and liabilities	(2,744)	(1,928)	1,469
Excess tax benefit from share-based compensation	—	(2,346)	(1,102)
Changes in assets and liabilities:			
Accounts receivable	(4,547)	2,911	(17,924)
Inventories	2,862	(11,975)	(1,075)
Prepaid expenses and other current and non-current assets	787	(388)	135
Restricted cash	(2,158)	1,187	(2,156)
Accounts payable	4,380	(651)	1,545
Accrued payroll and related expenses	1,247	1,055	1,083
Income taxes payable	(1,036)	(3,523)	(119)
Deferred grant revenue	4,301	(127)	2,156
Other current and non-current liabilities	1,302	(7)	522
Net cash provided by operating activities	35,686	25,682	19,633
INVESTING ACTIVITIES			
Acquisitions of property and equipment	(11,149)	(20,821)	(12,221)
Acquisition of BioHelix, net of cash acquired	—	(9,184)	—
Acquisition of AnDiaTec	—	(2,250)	—
Acquisition of intangibles	(92)	(1,680)	(15,501)
Purchase of business	—	—	(1,000)
Proceeds from sale of fixed assets	—	—	122
Net cash used for investing activities	(11,241)	(33,935)	(28,600)
FINANCING ACTIVITIES			
Proceeds from issuance of convertible senior notes	172,500	—	—
Proceeds from issuance of common stock, net of cancellations	4,781	7,928	4,664
Payments of debt issuance costs	(4,712)	—	—
Excess tax benefit from share-based compensation	—	2,346	1,102
Payments on lease obligation	(441)	(380)	(329)
Repurchases of common stock	(1,956)	(2,157)	(3,407)
Payments on line of credit	—	(5,000)	(37,000)
Payment of note payable to state agency	—	—	(1,498)
Payments on acquisition contingencies	(2,112)	(947)	—
Other	—	—	(1,041)
Net cash provided by (used for) financing activities	168,060	1,790	(37,509)
Effect of exchange rate changes on cash	2	(5)	—

Net increase (decrease) in cash and cash equivalents	192,507	(6,468)	(46,476)
Cash and cash equivalents, beginning of period	8,388	14,856	61,332
Cash and cash equivalents, at end of period	$200,895	$8,388	$14,856

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid during the period for interest	$981	$1,807	$2,086
Cash paid during the period for income taxes	$327	$2,211	$—
NON-CASH INVESTING ACTIVITIES			
Purchase of capital equipment by incurring current liabilities	$900	$172	$1,086
Purchase of licensed technology by incurring current liabilities	$—	$—	$108
Lease incentive for tenant improvements	$—	$1,658	$—
NON-CASH FINANCING ACTIVITIES			
Decrease of accrued payroll and related expenses upon issuance of common stock	$663	$456	$917
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 testing solutions primarily include applications in infectious diseases, women's health and gastrointestinal diseases. 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.
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. 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 $8.2 million and $5.8 million at December 31, 2014 and 2013, respectively.
Concentration of Credit Risk—Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable.
The Company invests its cash equivalents primarily in certificates of deposit and money market funds. Cash equivalents are maintained with high quality institutions.
The Company's trade accounts receivable are primarily derived from sales to medical distributors, hospitals and reference laboratories in the U.S. (see Note 7). 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 by evaluation of collection 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 method) or market. 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 $2.2 million and $0.6 million at December 31, 2014 and 2013, respectively (in thousands):

	December 31,	
	2014	2013
Raw materials	$10,472	$11,938
Work-in-process (materials, labor and overhead)	6,834	9,831
Finished goods (materials, labor and overhead)	7,457	5,870
Total inventories	$24,763	$27,639

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 shorter of the lease term or the estimated useful lives of the assets. The total expense for depreciation of fixed assets and amortization of leasehold improvements was $10.3 million, $7.9 million and $7.3 million for the years ended December 31, 2014, 2013 and 2012, respectively. Maintenance and minor repairs are charged to operations as incurred.

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

	December 31,	
	2014	2013
Equipment, furniture and fixtures	$64,233	$69,103
Building and improvements	32,074	25,964
Leased instruments	12,395	7,223
Land	1,080	1,080
Total property, plant and equipment, gross	109,782	103,370
Less: accumulated depreciation and amortization	(60,556)	(55,313)
Total property, plant and equipment, net	$49,226	$48,057

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 and in-process research and development. 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 $0.6 million, $0.3 million and $0.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. Goodwill and intangible assets consisted of the following (dollar amounts in thousands):

		December 31, 2014			December 31, 2013		
Description	Weighted-average useful life (years)	Gross assets	Accumulated amortization	Net	Gross assets	Accumulated amortization	Net
Goodwill	Indefinite	$84,197	$ (3,449)	$80,748	$84,212	$ (3,449)	$80,763
Purchased technology	8.4	51,870	(28,570)	23,300	51,870	(22,287)	29,583
Customer relationships	7.5	7,214	(3,978)	3,236	7,250	(2,954)	4,296
In-process research and development	Indefinite	690	—	690	2,260	—	2,260
License agreements	5.9	34,324	(30,050)	4,274	34,330	(21,374)	12,956
Patent and trademark costs	12.3	10,530	(1,725)	8,805	10,530	(861)	9,669
Software development costs	5	2,849	(1,264)	1,585	4,191	(693)	3,498
Total goodwill and intangible assets		$191,674	$ (69,036)	$122,638	$194,643	$ (51,618)	$143,025

The Company acquired distribution rights for $0.8 million in conjunction with the March 2013 Agreement with Life Technologies Corporation (see “Collaborative Arrangement” in Note 1). The distribution rights will be amortized on a straight-line basis over the contractual term of six years.

Amortization expense was $17.4 million, $16.6 million and $15.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. Included in amortization expense for 2014, 2013 and 2012 is $8.0 million 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 remaining amortization expense associated with this intangible asset is expected to be $0.7 million 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
2015	$10,044
2016	9,210
2017	8,913
2018	3,342
2019	2,085
Thereafter	7,606
Total	$41,200

The Company recorded a $1.6 million impairment loss related to a discontinued research and development named Project Stella during the third quarter of 2014. See further discussion in Note 10. The Company completed its annual evaluation for impairment of goodwill and in-process research and development as of December 31, 2014 and determined that no impairment of goodwill and no additional impairments of indefinite lived intangible assets existed.

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, 2013 and 2012.

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

	December 31,	
	2014	2013
Customer incentives	$4,233	$3,068
Accrued research and development costs	990	240
Other	2,820	2,303
Total other current liabilities	$8,043	$5,611

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 which 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 shorter of the lease term or 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 also earns income from the licensing of technology.

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 and expects to receive the remaining milestone payments of up to $2.4 million in 2015 and $2.8 million in 2016. Under the original and amended grant agreements, the Company recognizes grant revenue on 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, 2014, 2013 and 2012, we recognized $6.3 million, $2.6 million and $0.5 million as grant revenue, respectively. The Company classified $3.1 million and $1.0 million of funds received from the Bill and Melinda Gates Foundation as restricted cash as of December 31, 2014 and 2013, respectively. In addition, the Company classified $6.3 million and $2.0 million as deferred grant revenue as of December 31, 2014 and 2013, respectively.

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.

Collaborative Arrangement— In July 2012, the Company entered into a collaborative arrangement with Life Technologies Corporation for the development of molecular assays. ASC Topic 808, Collaborative Arrangements ("ASC Topic 808"), defines a collaborative arrangement as an arrangement where the parties are active participants and have exposure to significant risks. The Company is accounting for the joint development and commercialization activities with the third-party as a joint risk sharing collaboration in accordance with ASC Topic 808. Payments from Life Technologies Corporation totaled $0.4 million in 2014, $1.4 million in 2013 and $3.0 million in 2012. The

Company does not expect additional payments in 2015, as the development efforts are complete. The reimbursement represents 50% of project development costs based upon mutually agreed upon project plans for each molecular assay. In connection with the collaboration agreement, the Company also entered into a manufacturing and supply agreement with the same third party. As part of that agreement, and upon commercialization, the Company will manufacture and sell assays to the third party at cost plus 20%. Additionally, the Company will receive 40% of the gross margin for sales from the third party to the end customer. In March 2013, the Company entered into a six year instrument supply agreement (the “March 2013 Agreement”) with Life Technologies Corporation. Pursuant to the March 2013 Agreement, the Company paid $0.8 million for distribution rights to sell Life Technologies Corpor

ation's QuantStudio™ DX diagnostic laboratory instrument for use in the infectious disease field, along with the assays developed under the collaborative agreement. The distribution rights are included in intangible assets on the Consolidated Balance Sheets and are being amortized on a straight-line basis over the contractual term of six years.

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 $2.3 million, $2.2 million and $1.6 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Advertising Costs—Advertising costs are expensed as incurred. Advertising costs were $0.4 million, $0.7 million and $0.2 million for the years ended December 31, 2014, 2013 and 2012, 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. Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of trade accounts receivable. The Company establishes reserves for estimated uncollectible accounts and believes its reserves are adequate.

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 award. 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 ("stock awards") is measured at the grant date and recognized ratably over the vesting period. The fair value of stock awards 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 twelve months ended December 31, 2014, basic (loss) earnings per share were computed by dividing net (loss) earnings by the weighted-average number of common shares outstanding, including vested restricted stock awards, during the period. Diluted earnings per share 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 awards. 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 awards. For periods in which the Company incurs losses, potentially dilutive shares are not considered in the calculation of net loss per share as their effect would be anti-dilutive. For periods in which the Company has

57

earnings, stock options are excluded from the calculation of diluted net income per share 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. For the twelve months ended December 31, 2014, there were no differences between the number of common shares used for the basic and diluted earnings per share ("EPS") computation as the Company incurred a net loss. For the twelve months ended December 31, 2014, 1.1 million stock options and shares of restricted stock were excluded from diluted loss per share that would have been included if the Company had been in a net income position. Additionally, stock options totaling 1.0 million for the twelve months ended December 31, 2014 were not included in the computation of diluted earnings per share as their effect was anti-dilutive. As discussed in Note 2, the Company issued Convertible Senior Notes ("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 shares of common stock ("conversion premium"). No conversion premium existed as of December 31, 2014, therefore, there was no dilutive impact from the Convertible Senior Notes to EPS. In addition, for the twelve months ended December 31, 2014, there were no participating securities. As such, the treasury stock method was applied in calculating EPS rather than the more dilutive of the treasury stock or the two-class method, as performed in previous periods.

For the twelve months ended December 31, 2013 and 2012, diluted net income per share was reported based on the more dilutive of the treasury stock or the two-class method. Under the two-class method, net income is allocated to common stock and participating securities. For the twelve months ended December 31, 2013 and 2012, the Company's unvested restricted stock awards and certain unvested restricted stock units met the definition of participating securities. Basic net income per share under the two-class method was computed by dividing net income adjusted for earnings allocated to unvested stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net income per share under the two-class method was computed by dividing net income adjusted for earnings allocated to unvested stockholders for the period by the weighted average number of common and common equivalent shares outstanding during the period. The Company excludes stock options from the calculation of diluted net income per share 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 0.5 million and 1.1 million for the twelve months ended December 31, 2013 and 2012, respectively, were not included in the computation of diluted EPS because the exercise of such options would be anti-dilutive.

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2013 and 2012 (in thousands, except per share amounts):

	2013	2012
Basic net income per share:		
Net income	$7,390	$4,993
Less: income allocated to participating securities	(17)	(28)
Net income allocated to common stockholders	$7,373	$4,965
Weighted average common shares outstanding — basic	33,836	33,068
Net income per share — basic	$0.22	$0.15
Diluted net income per share:		
Net income	$7,390	$4,993
Less: income allocated to participating securities	(16)	(27)
Net income allocated to common stockholders	$7,374	$4,966
Weighted average common shares outstanding — basic	33,836	33,068
Dilutive securities	1,111	634
Weighted average common shares outstanding — diluted	34,947	33,702
Net income per share — diluted	$0.21	$0.15

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

Facility Restructuring— In 2013, the Company announced a plan to move its manufacturing operations in Santa Clara, California to Athens, Ohio. Termination benefits for those employees who choose not to relocate are accounted for in

accordance with ASC Topic 712, Compensation – Nonretirement Postemployment Benefits, and are recorded when it is probable that employees will be entitled to benefits and the amounts can be reasonably estimated. Estimates of termination benefits are based on the frequency of past termination benefits and the similarity of benefits under the current plan and prior plans. Facility related costs are accounted for in accordance with ASC Topic 420, Exit or Disposal Cost Obligations, and are recorded when the liability is incurred. The Company recorded a charge of $1.8 million during the year ended December 31, 2013, which included employee termination benefits and impairment charges related to the facility lease. The Company recorded no restructuring charges during the year ended December 31, 2014.

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 December 28, 2014, December 29, 2013 and December 30, 2012. For ease of reference, the calendar quarter end dates are used herein.

Reclassifications – The Company recorded immaterial reclassifications of $0.7 million and $0.8 million for the years ended December 31, 2013 and December 31, 2012, respectively, from general and administrative expense as previously reported in the Consolidated Statements of Operations to conform to current year interest expense presentation. The amortization of debt issuance costs and loan commitment fees had previously been recorded in general and administrative expense in the Consolidated Statements of Operations and the Company reclassified the amounts to more appropriately identify them as interest expense. The reclassification did not impact net income as previously reported or any prior amounts reported on the Consolidated Balance Sheets, Statements of Cash Flows, Statements of Comprehensive (Loss) Income or Statements of Stockholders' Equity. Management evaluated the materiality of these prior year reclassifications both qualitatively and quantitatively and determined that these errors were not material to the previously reported financial statements.

Recent Accounting Pronouncements—In May 2014, the FASB issued guidance codified in ASC Topic 606, Revenue Recognition—Revenue from Contracts with Customers, which amends the guidance in former ASC Topic 605, Revenue Recognition. This guidance is intended to improve and converge with international standards the financial reporting requirements for revenue from contracts with customers. 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 guidance is effective for annual reporting periods beginning after December 15, 2016, with early adoption prohibited. The Company is currently evaluating the impact of this guidance and expects to adopt the standard in the first quarter of 2017.

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 have to 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 is currently evaluating the impact of this guidance

and expects to adopt the standard for the annual reporting period ended December 31, 2016.

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 being amortized using the effective interest method to interest expense over the six-year term of the Senior Notes. The remaining $0.9 million of debt issuance costs were allocated as a component of equity in additional paid-in capital. As of December 31, 2014, the Company had deferred issuance costs related to the Convertible Senior Notes of $0.6 million included as a portion of prepaid expenses and other current assets and $3.5 million included as a portion of other non-current assets.

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, only 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 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 conversion value over 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, 2014, the Company recorded interest expense of $0.3 million related to the amortization of the debt discount and interest expense of $0.3 million related to the coupon due semi-annually on the Convertible Senior Notes.

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 has 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 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 as the Convertible Senior Notes were not considered redeemable.

As a policy election under applicable guidance related to the calculation of diluted net earnings per share, 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 December 31, 2014. If the Convertible Senior Notes were converted as of December 31, 2014, the if-converted value would not exceed the principal amount.

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, 2014
Principal amount of convertible notes outstanding	$172,500
Unamortized discount of liability component	(30,403)
Net carrying amount of liability component	142,097

Less: current portion	—
Long-term debt	$142,097
Carrying value of equity component, net of issuance costs	$29,758
Fair value of outstanding convertible senior notes	142,097
Remaining amortization period of discount on the liability component	6 years

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 matures on August 10, 2017. As part of this amendment, the Company incurred an additional $1.0 million in deferred financing costs related to the Senior Credit Facility. The Company had previously recorded deferred financing costs of $0.6 million related to its prior credit facility. Deferred financing costs are amortized on a straight-line basis over the term of the Senior Credit Facility. As of December 31, 2014 the Company had deferred financing costs related to the Senior Credit Facility of $0.5 million included as a portion of other non-current assets and $0.3 million included as a portion of prepaid expenses and other current assets. As of December 31, 2013, $1.2 million of deferred financing costs were included as a portion of other non-current assets. The Senior Credit Facility bears interest at either the London Interbank Offered Rate ("LIBOR") or the base rate, plus, in each case, an applicable margin. The base rate is equal to the highest of (i) the lender's prime rate, (ii) the federal funds rate plus one-half of one percent and (iii) LIBOR plus one percent. The applicable margin is generally determined in accordance with a performance pricing grid based on the Company's leverage ratio and ranges from 1.25% to 2.50% for LIBOR rate loans and from 0.25% to 1.50% for base rate loans. The agreement governing the Senior Credit Facility is subject to certain customary limitations, including among others: limitation on liens; limitation on mergers, consolidations and dispositions of assets; limitation on debt; limitation on dividends, stock redemptions and the redemption and/or prepayment of other debt; limitation on investments (including loans and advances) and acquisitions; and limitation on transactions with affiliates. On December 1, 2014, the Company amended the Senior Credit Facility to allow the conversion of, payment of principle or premiums on, and payment of interest on permitted convertible indebtedness. Additional terms were set forth to encompass the Convertible Senior Note offering discussed above. The Company is also subject to financial covenants which include a funded debt to adjusted EBITDA ratio (as defined in the Senior Credit Facility, with adjusted EBITDA generally calculated as earnings before, among other adjustments, interest, taxes, depreciation, amortization, and stock-based compensation) not to exceed 3:1 as of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:1 as of the end of each fiscal quarter. The Senior Credit Facility is secured by substantially all present and future domestic assets and properties of the Company and is senior to the Convertible Senior Notes.

As of December 31, 2014, the Company had no borrowings outstanding and had $95.7 million available to borrow under the Senior Credit Facility. The Company's ability to borrow under the Senior Credit Facility fluctuates from time to time due to, among other factors, the Company's borrowings under the facility and its funded debt to adjusted EBITDA ratio. As of December 31, 2013, the Company had no borrowings outstanding under the Senior Credit Facility. As of December 31, 2014 and 2013, the Company was in compliance with all financial covenants.

Note 3. Income Taxes

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

	December 31,		
	2014	2013	2012
Current:			
Federal	$61	$(565)	$1,870
State	(1,294)	810	377
Foreign	69	18	—
Total current provision	(1,164)	263	2,247
Deferred:			
Federal	(5,267)	(2,584)	811
State	2,488	(1,635)	(440)
Foreign	34	—	—
Total deferred (benefit) provision	(2,745)	(4,219)	371
(Benefit) provision for income taxes	$(3,909)	$(3,956)	$2,618

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,		
	2014	2013	2012
United States	$(11,328)	$3,364	$7,611
Foreign	345	70	—
	$(10,983)	$3,434	$7,611

Significant components of the Company's deferred tax assets as of December 31, 2014 and 2013 are shown below (in thousands).

	December 31,	
	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	$2,236	$1,486
Intangible assets	3,366	2,936
Sale-leaseback, net	1,424	1,602
Allowance for returns and discounts	4,574	3,155
Stock compensation	8,255	8,192
Tax credit carryforwards	2,060	1,351
Other, net	4,472	4,764
Total deferred tax assets	26,387	23,486
Valuation allowance for deferred tax assets	(2,331)	—
Total deferred tax assets, net of valuation allowance	24,056	23,486
Deferred tax liabilities:		
Convertible senior notes	(11,267)	—
Intangible assets	(12,939)	(16,494)
Property, plant and equipment	(6,424)	(4,948)
Total deferred tax liabilities	(30,630)	(21,442)
Net deferred tax assets and liabilities	$(6,574)	$2,044

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 that the cumulative before-tax results incurred over the three-year period ended December 31, 2014 were slightly profitable. 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, 2014, the Company recorded a valuation allowance of $2.3 million, which represents the portion of the deferred tax asset that management could no longer conclude was more likely than not to be realized. The amount of the deferred tax asset considered realizable, however, could be adjusted in the future based on changes in available evidence, such as if objective negative evidence in the form of near break-even results is no longer present and additional weight may be given to subjective evidence such as the Company's projections for profitability. During the year ended December 31, 2014, the valuation allowance increased by $2.3 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, 2014 and 2013, deferred tax assets do not include $1.5 million and $1.0 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 $1.5 million if such excess tax benefits are realized.

As of December 31, 2014, the Company had federal NOL carryforwards of approximately $6.0 million which will begin to expire in 2018, unless previously utilized. The Company also had state NOLs of approximately $16.6 million which will begin to expire in 2030. The Company has federal research credits of $2.3 million which will begin to

expire on December 31, 2033, unless previously utilized. 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 $7.0 million which do not expire.
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 reconciliation of income tax computed at the federal statutory rate to the (benefit) provision for income taxes from continuing operations is as follows (in thousands):

	Year ended December 31,		
	2014	2013	2012
Tax (benefit) expense at statutory tax rate	(3,844)	1,214	2,664
State (benefit) taxes, net of federal tax (benefit)	(151)	63	239
Permanent differences	70	(76)	26
Federal and state research credits—current year	(765)	(1,046)	(370)
Federal research credits - prior year	—	(527)	—
(Release) accrual of uncertain tax positions	(21)	369	(106)
Expiration of statutes for uncertain tax positions	(953)	(3,452)	—
Foreign effective tax rate differential	(18)	(6)	—
Impact of change in federal and state tax rate on revaluing deferred tax assets	110	(581)	75
Change in valuation allowance	2,331	—	—
Acquisition related adjustments	(485)	—	—
Other	(183)	86	90
	(3,909)	(3,956)	2,618

On January 3, 2013, the American Taxpayer Relief Act of 2012 was signed into law reinstating the federal research and development credit for the 2012 and 2013 years. Accordingly, the Company recorded the benefit related to the 2012 federal research and development credit of approximately $0.5 million in the first quarter of 2013.

The Company considers earnings of its non-U.S. subsidiaries to be indefinitely reinvested in those operations. As of December 31, 2014, the Company has not made a provision for U.S. or additional foreign withholding taxes on approximately $0.2 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 for unrecognized tax benefits (in thousands):

	Year ended December 31,		
	2014	2013	2012
Beginning balance	$7,765	$9,051	$8,567
(Decreases) increases related to prior year tax positions	(68)	773	372
Increases related to current year tax positions	642	1,019	366
Decreases due to settlements	(42)	—	—
Expiration of the statute of limitations for the assessment of taxes	(1,232)	(3,078)	(254)
Ending balance	$7,065	$7,765	$9,051

As of December 31, 2014 and 2013, the unrecognized tax benefits of $7.1 million and $7.8 million, respectively, of which $5.2 million and $5.5 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 as of December 31, 2014 and $0.4 million as of December 31, 2013. Interest expense, net of accrued interest (reversed), in 2014, 2013, and 2012 was approximately $(0.2) million, $(0.3) million, and $0.2 million, respectively.

The Company is subject to periodic audits by domestic and foreign tax authorities. During 2013, the Company was notified by the Internal Revenue Service that the Congressional Joint Committee of Taxation had completed its review and proposed no changes to the Company's tax returns filed for the tax periods 2008 through 2010. As a result, the Company released tax reserves and related interest of approximately $3.5 million. 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, 2014 or 2013.

Restricted Stock. The Company grants time-based restricted stock awards and performance-based and time-based restricted stock units to certain officers, directors and management. Until the restrictions lapse, ownership of the affected shares of restricted stock awards or units granted to the Company's officers is conditional upon continuous employment with the Company. During the restricted period, only holders of restricted stock awards have full voting rights with respect to their shares of restricted stock, even though the restricted stock award remains subject to transfer restrictions and generally is subject to forfeiture upon termination of employment or service. If an officer or director terminates service before the restrictions lapse, the restricted stock award is repurchased by the Company from the individual and any compensation expense previously recognized would be reversed, thereby reducing the amount of stock-based compensation expense during that period.

For the years ended December 31, 2014, 2013 and 2012, the Company granted approximately 0.1 million shares of restricted stock awards and units to officers and management, which either have a time-based four-year vesting provision or performance-based vesting provisions. 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 wi

64

th 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.

The performance-based restricted stock units granted in March 2011 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, 2013. During the fourth quarter ended December 31, 2013, 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 $1.9 million for the year ended December 31, 2013.

The performance-based restricted stock units 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.

During the years ended December 31, 2014, 2013 and 2012, restricted stock units 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 grants of restricted stock units was $0.4 million, $0.4 million and $0.5 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Equity Incentive Plan. The Company grants options and other stock based awards to employees and non-employee directors under its Amended and Restated 2010 Equity Incentive Plan (the “2010 Plan”) and previously granted options under the Amended and Restated 2001 Equity Incentive Plan (the "2001 Plan"). The 2001 Plan was terminated at the time of adoption of the 2010 Plan, but the terminated Plan continues to govern outstanding options granted thereunder. The Company has stock options and other stock based awards 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 $4.16 to $27.91 per share, and generally vest over four years. As of December 31, 2014, approximately 2.2 million shares remained available for grant under the 2010 Plan. As of December 31, 2013, the Company had $0.5 million receivable for funds related to stock option exercises and the receivable is included as a deduction from additional paid-in capital within the issuance of common stock under equity compensation plans presented in the Consolidated Statements of Stockholders’ Equity. The Company had no receivables for funds related to stock option exercises as of December 31, 2014.

Employee Deferred Bonus Compensation Program. For the year ended December 31, 2014 and 2013, 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 2010 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 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, 2014, 1,078,816 shares had been sold under the Plan, leaving 171,184 shares available for future issuance.

Share Repurchase Program. On April 23, 2013, the Company announced that the Board of Directors authorized us 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. At December 31, 2014, $50.0 million remains available under this plan. The repurchase program will expire on April 22, 2015 unless extended by the Board of Directors. On December 20, 2013, the Company repurchased 37,709 shares of common stock based on the closing price of the Company’s stock on the date of the transaction

from a Member of the Board of Directors, in exchange for payment for the aggregate exercise of 76,687 stock options. The stock option exercise is included in the issuance of common stock under equity compensation plans and the repurchase is included in repurchases of common stock presented in the Consolidated Statements of Stockholders' Equity.

Shares Reserved for Future Issuance. At December 31, 2014, approximately 6.2 million shares of common stock were reserved under the Company's equity incentive plans and 171,184 shares were reserved for purchases under the ESPP.

Note 5. Stock-Based Compensation

Compensation expense related to the Company's share-based awards for the years ended December 31, 2014, 2013 and 2012 was $6.7 million, $8.8 million and $6.6 million, respectively, of which $4.3 million, $4.0 million and $3.8 million, respectively, related to stock options and $2.1 million, $4.0 million and $2.2 million, respectively, related to restricted stock ("stock awards"). For the years ended December 31, 2014, 2013 and 2012 the Company recorded $0.3 million, $0.8 million and $0.6 million in stock-based compensation expense, respectively, associated with the deferred bonus compensation program, described in Note 4. During the years ended December 31, 2014, 2013 and 2012, $0.3 million, $0.7 million and $0.5 million, respectively, were initially recorded as a component of accrued payroll and related expenses.

Total stock-based compensation expense, related to all of the Company's share-based awards, was comprised as follows (in millions):

	Year ended December 31,		
	2014	2013	2012
Cost of sales	$0.6	$0.8	$0.6
Research and development	1.1	1.9	1.1
Sales and marketing	1.1	0.9	0.6
General and administrative	3.9	5.2	4.3
	$6.7	$8.8	$6.6

Compensation expense capitalized to inventory and compensation expense related to the Company's ESPP were not material for the years ended December 31, 2014, 2013 and 2012.

Stock Options

Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option award. For stock option awards 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 award that has vested at that date. The total number of stock option awards expected to vest is adjusted by estimated forfeiture rates. The estimated fair value of each stock option award 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,					
	2014		2013		2012	
Risk-free interest rate	1.59	%	0.86	%	0.83	%
Expected option life (in years)	5.78		5.53		5.52	
Volatility rate	42	%	44	%	46	%
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 $10.96, $9.19 and $6.51 for options granted during the years ended December 31, 2014, 2013 and 2012, respectively. The total intrinsic value was $2.8 million, $8.1 million and $2.0 million for options exercised during the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, total unrecognized compensation expense related to stock options was approximately $6.0 million and the related weighted-average period over which it is expected to be recognized is approximately 2.1 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, 2012, 2013 and 2014 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, 2012	3,417	$12.60		
Granted	624	15.23		
Exercised	(351)	11.85		
Cancelled	(90)	11.94		
Outstanding at December 31, 2012	3,600	13.15		
Granted	529	22.36		
Exercised	(642)	12.16		
Cancelled	(13)	10.61		
Outstanding at December 31, 2013	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	6.08	$41,157
Vested and expected to vest at December 31, 2014	3,461	$16.04	5.97	$40,629
Exercisable at December 31, 2014	2,330	$13.33	4.89	$33,667
Available for future grant at December 31, 2014	2,162			

Stock Awards
The fair value of stock awards is determined based on the closing market price of the Company's common stock on the grant date. The Company grants both time-based and performance-based stock awards. Compensation expense for time-based stock awards is measured at the grant date and recognized ratably over the vesting period. A portion of the stock awards granted in 2012 and 2013 was performance-based and vesting is 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 stock award 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 stock award 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 stock award. See further discussion of amended performance metrics and the impact to stock-based compensation expense in Note 4.

A summary of the status of stock awards activity for the years ended December 31, 2012, 2013 and 2014 is as follows (in thousands, except price data):

	Shares	Weighted-average grant date fair value
Non-vested at January 1, 2012	502	$13.65
Granted	145	15.69
Vested	(107)	15.29
Forfeited	(18)	13.81
Non-vested at December 31, 2012	522	13.87
Granted	74	23.53
Vested	(141)	23.43
Forfeited	(1)	15.26
Non-vested at December 31, 2013	454	16.22
Granted	145	25.73
Vested	(174)	28.27
Forfeited	(23)	18.19
Non-vested at December 31, 2014	402	$14.84

In 2014, 2013 and 2012, the Company issued approximately 0.1 million restricted share units each year in exchange for the deferred bonus liability of $0.7 million , $0.4 million and $0.9 million, respectively.

The total amount of unrecognized compensation expense related to non-vested stock awards as of December 31, 2014 was approximately $1.9 million, which is expected to be recognized over a weighted-average period of approximately 2.6 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 2014 are as follows (in thousands):

Years ending December 31,	Operating Leases	Lease obligation
2015	$1,794	$1,134
2016	2,306	1,145
2017	1,837	1,152
2018	1,622	1,161
2019	1,669	1,171
Thereafter	3,514	1,018
Total minimum lease payments	$12,742	6,781
Less: amount representing interest		(1,655)
Present value of lease obligation		5,126
Less: current portion		(509)
Long-term lease obligation		$4,617

Rent expense under operating leases totaled approximately $3.3 million for the year ended December 31, 2014, $2.3 million for the year ended December 31, 2013 and $2.0 million for the year ended December 31, 2012.

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 non-current liabilities.

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 include a new ten-year lease term through December 2019, with options to extend the lease for up to three additional five-year periods. The Company is amortizing the lease obligation over the new lease term. The amount of the monthly rental payments remain the same under the amendment. In November 2014, the lease agreement was amended to extend the timing to exercise the option to purchase the general partner's interest in the partnership from November 2014 to April 2015 for a fixed price. 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 $1.1 million for each of the three years ended December 31, 2014, 2013 and 2012.

Purchase Commitments

The Company has $3.4 million in firm purchase commitments with respect to planned capital expenditures as of December 31, 2014.

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. At December 31, 2014 and 2013, the Company had $0.3 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 is effective as of April 1, 2011, amends 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 are subject to the Amendment. The effective life and related amortization of the licensed technology will be based on the higher of the percentage of usage or the straight-line method. This percentage of usage will be determined using the revenues generated from products covered by the patents that are 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 $8.0 million of amortization expense in both 2014, 2013 and 2012, included as a portion of cost of sales.

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 $0.9 million, $1.0 million and $1.4 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Research and Development Agreements

The Company has entered into various research and development agreements which 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, 2014, total future commitments under the terms of these agreements are estimated at $4.3 million. The commitments will fluctuate as we agree 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 $13.0 million upon achievement of certain research and development milestones and revenue targets through 2018. As of December 31, 2014, all research and development milestones have been achieved and payments have been disbursed. Payments totaling $2.1 million were disbursed during 2014. The fair value of the remaining contingent consideration related to the revenue royalty earn-out to be settled in cash is estimated based on the Monte Carlo Simulation Model. Due to changes in the estimated payments and a shorter discounting period, the fair value of the contingent consideration liabilities changed, resulting in a $0.8 million gain recorded to cost of sales in the Consolidated Statements of Operations during the year ended December 31, 2014. As of December 31, 2014, the current portion of the contingent consideration is $0.6 million and the non-current portion of the contingent consideration is $4.9 million.

In August 2013, the Company completed a business combination accomplished by acquiring 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 ($0.6 million based on the December 31, 2014 currency conversion rate) upon achievement of certain revenue targets through 2018. The fair value of the remaining contingent consideration related to the revenue royalty earn-out to be settled in cash is estimated based on the Monte Carlo Simulation Model. Due to changes in the estimated payments and a shorter discounting period, the fair value of the contingent consideration liabilities changed, resulting in a $0.1 million gain recorded to cost of sales in the Consolidated Statements of Operations during the year ended December 31, 2014. As of December 31, 2014 the current portion of the contingent consideration is $0.1 million and the non-current portion of the contingent consideration is $0.1 million. In addition, the Company agreed to pay the founder of AnDiaTec contingent payments of up to €3.0 million ($3.7 million based on the December 31, 2014 currency conversion rate) upon achievement of certain research and development milestones, subject to, continued employment. During the twelve months ended December 31, 2014, the Company paid $0.9 million for the achievement of agreed upon research and development milestones. In January 2015, the Company paid $0.4 million for the achievement of agreed upon research and development milestones. These costs are recorded as compensation expense included in research and development expense in the Consolidated Statements of Operations.

Note 7. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented 13%, 13% and 14% of total revenue for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014 and 2013, balances due from foreign customers, in U.S. dollars, were $5.5 million and $3.2 million, respectively.

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

	Year ended December 31,		
	2014	2013	2012
Customer:			
A	18%	16%	16%
B	19%	19%	18%
C	11%	8%	8%

	48	%	43	%	42	%

As of December 31, 2014 and 2013, accounts receivable from individual customers with balances due in excess of 10% of total accounts receivable totaled $23.7 million and $19.6 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 year ended December 31,		
	2014	2013	2014	2013	2012
Domestic	$49,052	$47,891	$158,302	$152,711	$134,239
Foreign	174	166	24,313	22,699	21,502
	$49,226	$48,057	$182,615	$175,410	$155,741

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

	Year ended December 31,		
	2014	2013	2012
Infectious disease	$130,416	$128,079	$110,982
Women's health	34,332	33,328	32,653
Gastrointestinal disease	7,414	6,622	6,328
Royalty, license fees and grant revenue	7,681	3,917	2,452
Other	2,772	3,464	3,326
	$182,615	$175,410	$155,741

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, 2014				December 31, 2013			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Cash equivalents	3,057	—	—	3,057	3,056	—	—	3,056
Total assets measured at fair value	$3,057	$—	$—	$3,057	$3,056	$—	$—	$3,056
Liabilities:								
Contingent consideration	—	—	5,756	5,756	—	—	8,808	8,808
Total liabilities measured at fair value	$—	$—	$5,756	$5,756	$—	$—	$8,808	$8,808

There were no transfers of assets or liabilities between Level 1, Level 2 and Level 3 categories of the fair value hierarchy during the years ended December 31, 2014 and 2013.

The Company used Level 1 inputs to determine the fair value of its cash equivalents, which primarily consist of funds held in a money market account, and as such, the carrying value of cash equivalents approximates fair value. As of December 31, 2014 and 2013, the carrying value of cash equivalents was $3.1 million.

The Company assesses the fair value of contingent consideration to be settled in cash related to acquisitions using the Monte Carlo Simulation Model for the royalty earn-out portions of the contingent liability and probability weighted models for the research and development earn-out. These are Level 3 measurements. Significant assumptions used in the measurement

include probabilities of achieving the remaining milestones and the discount rates, which depend on the milestone risk profiles. Due to changes in the estimated payments and a shorter discounting period, the fair value of the contingent consideration liabilities changed, resulting in a $0.9 million gain recorded to cost of sales in the Consolidated Statements of Operations during the year ended December 31, 2014.

Changes in estimated fair value of contingent consideration liabilities from December 31, 2013 through December 31, 2014 are as follows (in thousands):

	Contingent consideration liability (Level 3 measurement)
Balance at December 31, 2013	$8,808
Cash payments	(2,112)
Net gain recorded for fair value adjustments	(910)
Unrealized gain on foreign currency translation	(30)
Balance at December 31, 2014	$5,756

Note 9. Employee Benefit Plan

The Company has a defined contribution 401(k) plan (the “401(k) Plan”) covering all employees who are eligible to join the 401(k) Plan upon employment. Employee contributions are subject to a maximum limit by federal law. This Plan includes an employer match of 50% on the first 6% of pay contributed by the employee. The Company contributed approximately $1.1 million, $0.9 million and $0.8 million to the 401(k) Plan during the years ended December 31, 2014, 2013 and 2012, respectively.

Note 10. Impairment Loss

The Company originally acquired certain automated direct fluorescent antibody cell analyzer technology as part of its DHI acquisition in 2010. This technology and the related program named "Project Stella" or "Bobcat" continued in development or evaluation (both the technology and associated instrument system) since the acquisition. During the third quarter of 2014, the Company evaluated the potential cash flows related to Project Stella as well as potential sale of the assets or joint development opportunities with third parties. As a result of those activities, the Company identified indicators of impairment related to the Project Stella assets. These assets included $1.5 million of software development costs, $1.6 million of in-process research and development, and $0.3 million in manufacturing line costs. The Company completed an evaluation of the recoverability of the assets, which included cash flow analyses as well as pursuing a potential sale of the assets to third parties. Based on the analyses, the Company determined the carrying value was not recoverable and an impairment loss was measured by comparing the carrying value to the estimated fair value of the assets. The fair value of the Project Stella assets was estimated utilizing the discounted cash flow analysis. As a result, the Company recognized an impairment loss of $3.4 million in the third quarter of 2014, included in the Company's Consolidated Statements of Operations. Additionally, $0.2 million was included in the impairment loss related to the expense to terminate a manufacturing contract with a third party to manufacture Project Stella instruments. The Company recorded no further impairment charges for the year ended December 31, 2014.

Note 11. Selected Quarterly Financial Data (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
2014				
Total revenues	$46,673	$31,488	$40,857	$63,597
Cost of sales (excludes amortization of intangible assets)	20,247	15,902	16,768	21,263
Gross profit (1)	24,855	14,015	22,518	40,763
Total costs and expenses (3)	48,690	41,473	50,978	50,682
Net (loss) income	(1,512)	(6,908)	(5,767)	7,113
Basic net (loss) earnings per share	(0.04)	(0.20)	(0.17)	0.20
Diluted net (loss) earnings per share	(0.04)	(0.20)	(0.17)	0.20
2013				
Total revenues	$61,995	$29,706	$33,539	$50,170
Cost of sales (excludes amortization of intangible assets)	19,547	13,671	15,297	18,461
Gross profit (2)	41,010	14,524	16,695	30,126
Total costs and expenses (3)	44,640	36,659	39,334	49,935
Net income (loss)	12,367	(1,755)	(4,361)	1,139
Basic net earnings (loss) per share	0.37	(0.05)	(0.13)	0.03
Diluted net earnings (loss) per share	0.36	(0.05)	(0.13)	0.03

(1) Included in 2014 quarterly gross profit is amortization of intangible assets of $1.6 million, $1.6 million, $1.6 million and $1.5 million for the first quarter, second quarter, third quarter and fourth quarter, respectively.

(2) Included in 2013 quarterly gross profit is amortization of intangible assets of $1.4 million, $1.5 million, $1.5 million and $1.7 million for the first, second, third, and fourth quarters, respectively.

(3) Includes reclassification of $0.2 million, $0.2 million, $0.2 million, $0.1 million, and $0.2 million from general and administrative expense for the first, second, third, and fourth quarters of 2013 and the first quarter of 2014, respectively.

SCHEDULE II
QUIDEL CORPORATION
CONSOLIDATED VALUATION AND QUALIFYING ACCOUNTS

Description	Balance at beginning of period	Additions charged to expense or as reductions to revenue (1)	Deductions (2)	Balance at end of period
	(in thousands)			
Year ended December 31, 2014				
Accounts receivable allowance	$5,790	$23,447	$(21,016)	$8,221
Year ended December 31, 2013:				
Accounts receivable allowance	$4,955	$15,230	$(14,395)	$5,790
Year ended December 31, 2012:				
Accounts receivable allowance	$1,960	$10,849	$(7,854)	$4,955

(1) Represents charges associated primarily to accruals for early payment discounts, volume discounts and contract rebates recorded as reductions to revenue. Additions to allowance for doubtful accounts are recorded to sales and marketing expenses.

(2) The deductions represent actual charges against the accrual described above.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of disclosure controls and procedures: We have performed an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"). Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of December 31, 2014 to ensure that information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in internal control over financial reporting: There was no change in our internal control over financial reporting during the three months ended December 31, 2014 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's report on internal control over financial reporting: Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2014.

74

The effectiveness of our internal control over financial reporting as of December 31, 2014 has been audited by Ernst & Young LLP, our independent registered public accounting firm, as stated in their report which is included in this Item 9A.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and
Stockholders of Quidel Corporation

We have audited Quidel Corporation's internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Quidel Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Quidel Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Quidel Corporation as of December 31, 2014 and 2013, and the related consolidated statements of income, comprehensive (loss) income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2014 of Quidel Corporation and our report dated February 23, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 23, 2015

Item 9B. Other Information

2015 Annual Meeting of Stockholders

The Company's 2015 Annual Meeting of Stockholders will be held on Tuesday, May 5, 2015, beginning at 8:30 a.m. (local time) at the San Diego Marriott Del Mar, 11966 El Camino Real, San Diego, California 92130.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item (with respect to directors) is incorporated by reference to our 2015 Proxy Statement, which will be filed with the SEC no later than April 30, 2015. Information with respect to executive officers is included under Item 1 of this Annual Report.

The information required by this item is incorporated by reference from the information under the captions "Corporate Governance" and "Section 16(a) Beneficial Ownership Reporting Compliance," to be contained in our 2015 Proxy Statement.

Item 11. Executive Compensation

The information required by this item is incorporated by reference from the information under the captions "Director Compensation" and "Executive Compensation" to be contained in our 2015 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated by reference from the information under the captions "Securities Available for Issuance Under Our Equity Compensation Plans" and "Security Ownership of Certain Beneficial Owners and Management" to be contained in our 2015 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference from the information under the captions "Compensation Committee Interlocks and Insider Participation in Compensation Decisions," "Certain Relationships and Related Transactions" and "Corporate Governance" to be contained in our 2015 Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference from the information under the caption "Audit Committee Matters" to be contained in our 2015 Proxy Statement.

Part IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Form 10-K:

(a)(1) Financial Statements

The Consolidated Financial Statements required by this Item are submitted in Part II, Item 8 of this form 10-K.

(2) Financial Statement Schedules

The following Financial Statement Schedule of Quidel Corporation for the years ended December 31, 2014, 2013 and 2012 is filed as part of this Annual Report and should be read in conjunction with the Consolidated Financial Statements of Quidel Corporation:

Schedule II. Consolidated Valuation and Qualifying Accounts.
Financial Statement Schedules not listed above have been omitted because of the absence of conditions under which they are required or because the required information is included in the Consolidated Financial Statements or the Notes thereto.
(3) Exhibits. See Paragraph 15(b) below.

(b) Exhibits
The exhibits listed on the accompanying Exhibit Index immediately following the Financial Statement Schedule are filed as part of, and incorporated by reference into, this Annual Report on Form 10-K.

(c) Financial Statements required by Regulation S-X which are excluded from this Annual Report on Form 10-K by Rule 14(a)-3(b).
Not applicable.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of Quidel Corporation. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2010.)
3.2	Amended and Restated Bylaws of Quidel Corporation. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on May 21, 2012.)
4.1	Certificate of Designations of Series C Junior Participating Preferred Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2010.)
4.2	Specimen stock certification. (Incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-3 filed on August 31, 2010.)
4.3	Indenture, dated as of December 1, 2014, between the Registrant and The Bank of New York Mellon Trust Company, N.A. (Incorporated by reference to Exhibit 4.8 to the Registrant's Form S-3 filed on December 1, 2014.)
4.4	First Supplemental Indenture, dated as of December 8, 2014, by and between the Registrant and The Bank of New York Mellon Trust Company, N.A. (including the form of Notes). (Incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K filed on December 8, 2014.)
10.1(1)	Registrant's Amended and Restated 1983 Employee Stock Purchase Plan. (Incorporated by reference to Appendix B to the Registrant's Proxy Statement filed on April 6, 2012.)
10.2(1)	Registrant's Amended and Restated 2001 Equity Incentive Plan, effective as of May 12, 2009. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 18, 2009.)
10.3(1)	

	Quidel Corporation Amended and Restated 2010 Equity Incentive Plan. (Incorporated by reference to Appendix A to the Registrant's Proxy Statement filed on April 1, 2014.)
10.4(1)	Form of Notice of Grant of Award and Award Agreement for Quidel Corporation 2010 Equity Incentive Plan. (Incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-8 filed on May 14, 2010.)
10.5(1)	Form of Restricted Stock Award Agreement for Quidel Corporation 2010 Equity Incentive Plan. (Incorporated by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-8 filed on May 14, 2010.)
10.6	Settlement Agreement dated April 27, 2005 between the Registrant and Inverness Medical Innovations, Inc. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 3, 2005.)
10.7	Second Amendment to Quidel/Inverness Settlement Agreement dated September 27, 2011. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on September 28, 2011.)

10.8	Form of Single Tenant Absolute Net Lease. (Incorporated by reference to Exhibit 10.7 to the Registrant's Form 8-K filed on January 4, 2000.)
10.9	Second Amendment to Single Tenant Absolute Net Lease. (Incorporated by reference to Exhibit 10.1 to Registrant's Form 8-K filed on December 29, 2009.)
10.10(1)	Form of Indemnification Agreement—Corporate Officer and/or Director. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on August 23, 2005.)
10.11(1)	Employment Agreement, dated as of January 16, 2009, between the Registrant and Douglas C. Bryant. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 20, 2009.)
10.12(1)	Agreement Re: Change in Control, dated as of January 16, 2009, between the Registrant and Douglas C. Bryant. (Incorporated by reference to Exhibit 10.4 to the Registrant's Form 8-K filed on January 20, 2009.)
10.13(1)	Employment Offer Letter, entered into on June 5, 2008, between the Registrant and Robert J. Bujarski. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on June 6, 2008.)
10.14(1)	Agreement Re: Change in Control, entered into on June 5, 2008, between the Registrant and Robert J. Bujarski. (Incorporated by reference to Exhibit 10.2 to Registrant's Form 8-K filed on June 6, 2008.)
10.15(1)	Randall Steward Employment Offer Letter, dated as of September 12, 2011. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on October 21, 2011.)
10.16(1)	Agreement Re: Change in Control, dated as of September 19, 2011, between the Registrant and Randall Steward. (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on October 21, 2011.)
10.17(1)	Employment Offer Letter, dated May 9, 2011, between the Registrant and Mark W. Smits. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended June 30, 2011.)
10.18(1)	Agreement Re: Change in Control, entered into on May 11, 2011, between the Registrant and Mark W. Smits. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-Q for the quarter ended June 30, 2011.)
10.19(1)	Change in Control Agreement dated July 19, 2004 between the Registrant and Michael J. Beck. (Incorporated by reference to Exhibit 10.35 to the Registrant's Form 10-Q for the quarter ended June 30, 2004.)
10.20(1)	Agreement Re: Change in Control, entered into on November 7, 2008, between the Registrant and John D. Tamerius, Ph.D. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on November 7, 2008.)
10.21(1)	Employment Offer Letter, dated April 24, 2014, between the Registrant and Werner Kroll. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended June 30, 2014.)

10.22(1)	Agreement Re: Change in Control, entered into on May 9, 2014, between the Registrant and Werner Kroll. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-Q for the quarter ended June 30, 2014.)
10.23(1)	2012 Cash Bonus Awards to the Registrant's executive offices. (Incorporated by reference to Exhibit 10.5 of the Registrant's Form 8-K filed on March 1, 2013.)
10.24(1)	2013 Cash Incentive Compensation Plan for the Registrant. (Incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on March 1, 2013.)
10.25(1)	2013 Employee Deferred Bonus Compensation Program. (Incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on March 1, 2013.)
10.26(1)	2013 Equity Incentive Plan Grants to the Registrant's executive officers. (Incorporated by reference to Exhibit 10.3 of the Registrant's Form 8-K filed on March 1, 2013.)
10.27(1)	2013 Annual Base Salaries for the Registrant's executive officers, effective as of March 1, 2013. (Incorporated by reference to Exhibit 10.4 of the Registrant's Form 8-K filed on March 1, 2013.)
10.28(1)	2014 Cash Incentive Compensation Plan for the Registrant. (Incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on February 28, 2014.)
10.29(1)	2014 Employee Deferred Bonus Compensation Program. (Incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on February 28, 2014.)

10.30(1)	2014 Equity Incentive Plan Grants to the Registrant's executive officers. (Incorporated by reference to Exhibit 10.3 of the Registrant's Form 8-K filed on February 28, 2014.)
10.31(1)	2014 Annual Base Salaries for the Registrant's executive officers, effective as of February 28, 2014. (Incorporated by reference to Exhibit 10.4 of the Registrant's Form 8-K filed on February 28, 2014.)
10.32(1)	2015 Cash Incentive Compensation Plan for the Registrant. (Incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on February 9, 2015.)
10.33(1)	2015 Employee Deferred Bonus Compensation Program. (Incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on February 9, 2015.)
10.34(1)	2015 Equity Incentive Plan Grants to the Registrant's executive officers. (Incorporated by reference to Exhibit 10.3 of the Registrant's Form 8-K filed on February 9, 2015.)
10.35(1)	2015 Annual Base Salaries for the Registrant's executive officers, effective as of February 9, 2015. (Incorporated by reference to Exhibit 10.4 of the Registrant's Form 8-K filed on February 9, 2015.)
10.36	Amended and Restated Credit Agreement, by and among the Registrant, as Borrower, each lender from time to time party thereto (collectively, "Lenders" and individually, a "Lender") and Bank of America, N.A. as Agent, Swing Line Lender and L/C Issuer, dated as of August 10, 2012. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on August 10, 2012.)
10.37	Amended and Restated Security Agreement by and among the Registrant, as Borrower, the material subsidiaries of Borrower, each additional guarantor that may become a party thereto and Bank of America, N.A., as Agent, dated as of August 10, 2012. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on August 10, 2012.)
10.38	Amendment No. 2 to Credit Agreement, by and among the Registrant, as Borrower, the material subsidiaries of Borrower, each additional guarantor that may become a party thereto and Bank of America, N.A., as Agent, Swing Line Lender and L/C Issuer, dated as of December 1, 2014. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on December 4, 2014.)
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification by Principal Executive Officer of the Registrant pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by Principal Financial and Accounting Officer of the Registrant pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications by Principal Executive Officer and Principal Financial and Accounting Officer of the Registrant pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the

	Sarbanes-Oxley Act of 2002.
101	XBRL Instance Document
101	XBRL Taxonomy Extension Schema Document
101	XBRL Taxonomy Calculation Linkbase Document
101	XBRL Taxonomy Extension Definition Linkbase Document
101	XBRL Taxonomy Label Linkbase Document
101	XBRL Taxonomy Presentation Linkbase Document
*	Filed / furnished herewith

(1) Indicates a management plan or compensatory plan or arrangement.

SIGNATURES

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

QUIDEL CORPORATION
By /s/ DOUGLAS C. BRYANT
Douglas C. Bryant
President, Chief Executive Officer
(Principal Executive Officer)

Date: February 23, 2015

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

Signature	Title	Date
/s/ DOUGLAS C. BRYANT Douglas C. Bryant	President, Chief Executive Officer (Principal Executive Officer)	February 23, 2015
/s/ RANDALL J. STEWARD Randall J. Steward	Chief Financial Officer, (Principal Financial Officer)	February 23, 2015
/s/ MARK A. PULIDO Mark A. Pulido	Chairman of the Board	February 23, 2015
/s/ THOMAS D. BROWN Thomas D. Brown	Director	February 23, 2015
/s/ KENNETH F. BUECHLER Kenneth F. Buechler	Director	February 23, 2015
/s/ RODNEY F. DAMMEYER Rodney F. Dammeyer	Director	February 23, 2015
/s/ MARY LAKE POLAN Mary Lake Polan	Director	February 23, 2015
/s/ JACK W. SCHULER Jack W. Schuler	Director	February 23, 2015
/s/ KENNETH J. WIDDER Kenneth J. Widder	Director	February 23, 2015