QUIDEL CORP /DE/
Form 10-K
February 15, 2019

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, 2018
OR
.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from N/A to N/A
Commission file number: 0-10961
QUIDEL CORPORATION
(Exact name of registrant as specified in its charter)

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

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

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

Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 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 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 every Interactive Data File required to be submitted 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 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	x	Accelerated filer	¨
Non-accelerated filer	¨	Smaller reporting company	¨
		Emerging growth company	¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any ¨

new or revised financial accounting standards
provided pursuant to Section 13(a) of the Exchange
Act.

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $2,294,280,391 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 8, 2019, 39,446,667 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 2019 Annual Meeting of Stockholders (to be held on May 14, 2019) are incorporated by reference into Part III, Items 10, 11, 12, 13 and 14 of this Annual Report on Form 10-K

QUIDEL CORPORATION
FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018
TABLE OF CONTENTS

		Page
	A Warning About Forward-Looking Statements	3
	Part I	
Item 1.	Business	4
Item 1A.	Risk Factors	17
Item 1B.	Unresolved Staff Comments	31
Item 2.	Properties	32
Item 3.	Legal Proceedings	32
Item 4.	Mine Safety Disclosures	32
	Part II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	33
Item 6.	Selected Financial Data	35
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	36
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	47
Item 8.	Financial Statements and Supplementary Data	49
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	79
Item 9A.	Controls and Procedures	79
Item 9B.	Other Information	81
	Part III	
Item 10.	Directors, Executive Officers and Corporate Governance	82
Item 11.	Executive Compensation	82
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	82
Item 13.	Certain Relationships and Related Transactions, and Director Independence	82
Item 14.	Principal Accountant Fees and Services	82
	Part IV	
Item 15.	Exhibits and Financial Statement Schedules	83
Item 16.	Form 10-K Summary	87
	Signatures	88

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, those discussed in this Annual Report on Form 10-K in Part I, Item 1A "Risk Factors."

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," and similar words, although some forward-loo statements are expressed differently. Forward-looking statements in this Annual Report include, among others, statements concerning: our outlook for the upcoming fiscal year regarding revenue growth, gross margins and earnings, projected capital expenditures for the upcoming fiscal year; and our source of funds for such expenditures; the sufficiency of our liquidity and capital resources; our strategy, goals, initiatives and objectives; the anticipated beneficial attributes of products and platforms under development; anticipated new product and development results; our exposure to claims and litigation, including litigation currently pending against us involving Beckman Coulter; that we expect to continue to depend on a few key distributors for sales of our products; expected growth and the sources of that growth; the impact of new accounting standards; that point-of-care testing is increasing; that clinical reference laboratories will continue to be a competitive threat; that we will continue to make substantial expenditures for sales and marketing, manufacturing and product research and development activities; that influenza and cardiology revenues will be a significant portion of our total revenue; that integration costs will decline; industry consolidation and competition trends; competition for management and key personnel; that we may enter into additional foreign currency exchange hedging or risk sharing arrangements; the sufficiency of our facilities; the sufficiency of our insurance and our exposure to claims and litigation; our intention to not pay dividends; that we will continue to obtain licenses from third parties; and our intention to continue to evaluate technology and acquisition opportunities. The risks described under "Risk Factors" in Item 1A of this Annual Report and elsewhere herein and in reports and registration statements that we file with the Securities and Exchange Commission (the "SEC") from time to time, should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report. Except as required by law, we undertake no obligation to publicly release the results of any revision or update of these forward-looking statements, whether as a result of new information, future events or otherwise.

Part I

Item 1. Business

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

Overview

We have a leadership position in the development, manufacturing and marketing of rapid diagnostic testing solutions. These diagnostic testing solutions are separated into our four product categories: rapid immunoassays, cardiac immunoassays, specialized diagnostic solutions and molecular diagnostic solutions. We sell our products directly to end users and distributors, in each case, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, urgent care clinics, leading universities, retail clinics, pharmacies and wellness screening centers. We market our products through a network of distributors and through a direct sales force. The Company operates in one business segment that develops, manufactures and markets our four product categories.

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, cardiovascular diseases and conditions, women’s health, gastrointestinal diseases, autoimmune diseases, bone health and thyroid diseases.

Corporate Information

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

On October 6, 2017, we closed our acquisition of the Triage® MeterPro® Cardiovascular (CV) and toxicology business (“Triage Business”), and B-type Naturietic Peptide (BNP) assay business run on Beckman Coulter analyzers (“BNP Business” and, together, the “Triage and BNP Businesses”) from Alere Inc. (“Alere”). This strategic acquisition added an extensive
cardiovascular and toxicology point-of-care (POC) offering to our innovative medical diagnostics portfolio.

Business Strategy

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

- rapid immunoassay tests for use in physician offices, hospital laboratories and emergency departments, retail clinics, eye health settings, pharmacies and other urgent care or alternative site settings;
- cardiac immunoassay tests for use in physician offices, hospital laboratories and emergency departments, and other urgent care or alternative site settings;
- specialized diagnostic solutions, including direct fluorescent assays (“DFA”) and culture-based tests for the clinical virology laboratory and other products serving the bone health, autoimmune and complement research communities; and
- molecular diagnostic tests for use in hospitals, moderately complex physician offices, laboratories and other settings.

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

4

- leveraging our current infrastructure to develop and launch new Rapid Immunoassays and Cardiac Immunoassays such as additional assays for our Sofia® and Sofia® 2 analyzers and Triage® MeterPro® systems;
- developing a molecular diagnostics franchise that incorporates three distinct testing platforms, Solana®, AmpliVue®, and Savanna® and that leverages our molecular assay development competencies; and
- strengthening our position with distribution partners and our end-user customers to gain more emphasis on our products.

Our current initiatives to execute this strategy include the following:

- provide products that can compete effectively in the healthcare market where cost and quality are important;
- complete the integration of the Triage and BNP Businesses acquired in late 2017;
- strengthen and leverage our international infrastructure to support the integration of the Triage and BNP Businesses and enhance our global footprint to support our international operations and future growth;
- 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 strategy to develop differentiated technologies and products;
- strengthen our market and brand leadership in current markets by acquiring and/or developing and introducing clinically superior diagnostic solutions;
- strengthen our direct sales force to enhance relationships with integrated delivery networks, laboratories and hospitals, with a goal of driving growth through improved physician and laboratorian satisfaction;
- leverage our wireless connectivity and data management systems, including cloud-based tools;
- support payer evaluation of diagnostic tests and establishment of favorable reimbursement rates;
- provide clinicians with validated studies that encompass the clinical efficacy and economic efficiency of our diagnostic tests for the professional market;
- create strong global alliances to support our efforts to achieve leadership in key markets and expand our presence in emerging markets;
- further refine our manufacturing efficiencies and productivity improvements to increase profit; and
- focus on innovative products and markets and leverage our core competency in new product development.

The Overall Market for In Vitro Diagnostics

Customers for In Vitro Diagnostics (“IVD”) products are primarily centralized laboratories and decentralized POC or alternate settings.

Centralized testing market

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

Decentralized POC market

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).

- Out-of-hospital testing sites consist of physicians’ office laboratories, nursing homes, pharmacies, eye health offices, retail clinics and other non-institutional, ambulatory settings in which healthcare providers perform diagnostic tests.
- 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 has 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. The decentralized POC market utilizes a large variety of IVD products ranging from moderate-sized instrumented diagnostic systems serving larger group practices to single-use, disposable tests. We believe POC testing is increasing due to its clinical benefit, fast results, cost-effectiveness and patient satisfaction.

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

Products

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

System Platforms:

Our diagnostic testing solutions are separated into our four product categories: rapid immunoassay, cardiac immunoassay, specialized diagnostic solutions and molecular diagnostic solutions. The key product categories and platforms are described below:

Rapid Immunoassay

Sofia and Sofia 2 Analyzers. Sofia is the brand name for our fluorescent immunoassay ("FIA") systems. The easy-to-use Sofia and Sofia 2 analyzers combine unique software and 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. We launched the Sofia analyzer in 2011 and Sofia 2 in 2017. These systems provide 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. Sofia 2 systems include additional benefits and features at a cost point that allows us to better address the lower-volume segment of the diagnostic testing market. Sofia 2 analyzers also incorporate enhanced optics, which provide added performance benefits and enable positive test results to be read in as few as three minutes.

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

InflammaDry and AdenoPlus. The InflammaDry and AdenoPlus products are rapid, lateral-flow based, POC products for the detection of infectious and inflammatory diseases and conditions of the eye. InflammaDry is a test that detects elevated levels of MMP-9, a key inflammatory marker for dry eye. AdenoPlus is a test that differentiates between a viral and bacterial infection of acute conjunctivitis (pink eye). Both products utilize innovative patented technology, are CE marked, FDA-cleared and CLIA-waived.

Cardiac Immunoassay

Triage MeterPro. Triage MeterPro is our portable testing platform that runs a comprehensive menu of tests that enable physicians to promote improved health outcomes through the rapid diagnosis of critical diseases and health conditions, as well as the detection of certain drugs of abuse. This system aids in the diagnosis, assessment and risk stratification of patients having critical care issues, including congestive heart failure, acute coronary syndromes, acute myocardial infarction, or AMI, and can reduce hospital admissions and improve clinical and economic outcomes. Triage cardiovascular rapid tests include immunoassays for B-type Natriuretic Peptide (BNP), creatine kinase-MB (CK-MB), d-dimer, myoglobin, troponin I and N-terminal pro-Brain Natriuretic Peptide (NT-proBNP). Triage tests for troponin I, high sensitivity Troponin I, PLGF and NT-proBNP, as well as certain test panels which include a combination of immunoassays, are not available for sale in the United States.

We also offer a version of the Triage BNP Test for use on Beckman Coulter lab analyzers.

In addition to the cardiovascular menu, the Triage TOX Drug Screen provides qualitative results for the determination of the presence of drug and/or the major metabolites in urine including assays for acetaminophen/paracetamol, amphetamines,

6

methamphetamines, barbiturates, benzodiazepines, cocaine, methadone, opiates, phencyclidine, THC and tricyclic antidepressants.

Specialized Diagnostic Solutions

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

Specialty Products. We provide a variety of biomarkers for bone health and 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 to monitor the effectiveness of therapy in pharmaceutical and related research. In the area of autoimmune disease, we have developed Enzyme Linked Immunosorbent Assays ("ELISA") and reagents for the detection of activation products from the three main Complement Pathways. Assays are developed on a microwell platform and are currently marketed to clinicians and researchers. We currently sell these products both directly and through select distributors throughout the world under the Quidel and MicroVue brands.

Molecular Diagnostic Solutions

AmpliVue. With our 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 medical and wellness categories discussion below.

Solana. The Solana system was developed using our proprietary HDA technology and leverages our AmpliVue product lines. Solana is an easy to run amplification and detection system that has the ability to concurrently run up to 12 assays at a time.

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 medical and wellness categories discussion below.

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

Connectivity and Data Management

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

Medical and Wellness Categories:

Our products address the following medical and wellness categories, among others:

Infectious Diseases

Influenza. We offer a variety of products designed to detect the viral antigens of influenza type A and B utilizing fluorescent immunoassay, lateral flow and molecular technologies. Our Sofia Influenza A+B test, used in conjunction with our Sofia and Sofia 2 analyzers, 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, we offer molecular testing options with Solana Influenza A+B assay and our Lyra Influenza A+B real-time PCR assay.

Streptococci. We offer a number of products designed to detect Streptococcal infections utilizing fluorescent immunoassay, lateral flow and molecular technologies. Our Sofia Strep A and Strep A+ fluorescent immunoassays, used in conjunction with our Sofia and Sofia 2 analyzers, and our QuickVue Strep A tests are intended for the rapid, qualitative

7

detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture. Our Solana Strep Complete and Solana Group A Strep Assays allow for the rapid, qualitative detection of Group A and pyogenic Group C/G Strep and Group A Strep, respectively, utilizing our molecular HDA technology. In addition, our Lyra Direct Strep Assay is a multiplex real-time PCR assay that detects and differentiates between pyogenic Group A and pyogenic C or G Streptococcal throat infections.

RSV (and hMPV). Our Sofia RSV test and our QuickVue RSV test are rapid immunoassay tests for Respiratory Syncytial Virus ("RSV"). In addition, we offer molecular testing options with our Solana RSV + human metapneumovirus (hMPV) test and our combo Quidel Lyra RSV + human metapneumovirus (hMPV) test. The majority of upper respiratory tract infections in children is caused by viruses, and RSV is generally recognized as a frequent agent responsible for these infections and shares overlapping symptoms with hMPV.

Herpes and Herpes Family. We offer several products designed to detect various herpes simplex virus ("HSV") and herpes family viruses utilizing molecular and cell culture technologies. We offer our Solana HSV-1+2/VZV Assay, used in conjunction with our Solana instrument, for the detection of HSV type 1, HSV type 2, and varicella-zoster virus ("VZV"). We also offer our Lyra Direct HSV 1+2/VZV and AmpliVue HSV 1+2 assays. In addition, our proprietary engineered cell culture system, ELVIS HSV, is an FDA cleared and highly sensitive system for the isolation and detection of HSV types 1 and 2. We also provide a multiplex cell culture solution using a propriety cell platform called H&V-Mix™ that is used to isolate HSV, VZV and Cytomegalovirus, all in the herpes family of viruses. Antibody detection and identification of each of these viruses can be performed with FDA cleared antibody products provided under the D3 DFA brand. HSV is a widespread sexually transmitted infection. VZV is a DNA virus of the family Herpesviridae; infection results in chickenpox (varicella) and may lead to complications such as pneumonia and may reactivate later in life to produce shingles.

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

Lyme. Our Sofia Lyme FIA, used in conjunction with our Sofia analyzers, was FDA cleared in 2017. The assay is used to aid in the rapid differential detection of human IgM and IgG antibodies to Borrelia burgdorferi from serum and plasma specimens from patients suspected of B. burgdorferi infection and is intended for use to aid in the diagnosis of Lyme disease, a tickborne disease. In 2018, we received 510(k) clearance and CLIA waiver from the FDA to market Sofia 2 Lyme FIA, which is used with the Sofia 2 Fluorescent Immunoassay analyzer for the rapid differential detection of human IgM and IgG antibodies to Borrelia burgdorferi from finger-stick whole blood specimens from patients suspected of B. burgdorferi infection. In addition, our Sofia 2 Lyme+ assay is CE marked for use in the rapid differential detection of human IgM and IgG antibodies to Borrelia burgdorferi, Borrelia garinii, and Borrelia afzelii from serum and plasma specimens. These tests are intended for use with the Sofia 2 analyzer to aid in the diagnosis of Lyme disease in the U.S. and European markets.

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

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

Bordetella Pertussis. Our AmpliVue and Solana Bordetella assays are used in detection of Bordetella pertussis. Pertussis, or whooping cough, is a very contagious disease caused by the Bordetella pertussis bacteria and there has been increasing incidence in recent years. Our Solana Bordetella Complete Assay is used for the qualitative detection

and differentiation of Bordetella pertussis and Bordetella parapertussis nucleic acids isolated from nasopharyngeal swab specimens obtained from patients suspected of having a respiratory tract infection attributable to Bordetella pertussis and Bordetella parapertussis.

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

Cardiology

The cardiology diagnostic market includes the markets for heart failure diagnostics, coronary artery disease risk assessment, coagulation testing and acute coronary syndrome. Our 2017 acquisitions of the Triage and BNP Businesses have positioned us to become a leader in this market. The Triage system consists of a portable fluorometer that interprets consumable test devices for cardiovascular conditions, as well as the detection of drugs of abuse. The Triage cardiovascular tests include the following:

Triage BNP Test. An immunoassay that measures B-type Natriuretic Peptide (BNP) in whole blood or plasma, used as an aid in the diagnosis and assessment of severity of heart failure. The test is also used for the risk stratification of patients with acute coronary syndromes and heart failure.

Triage Cardiac Panel. An immunoassay for the quantitative determination of CK-MB, myoglobin and troponin I in whole blood or plasma, as an aid in the diagnosis of AMI.

Triage Profiler S.O.B. An immunoassay for use as an aid in the diagnosis of myocardial infarction (MI), the diagnosis and assessment of severity of congestive heart failure, the assessment and evaluation of patients suspected of having disseminated intravascular coagulation and thromboembolic events, including pulmonary embolism and deep vein thrombosis, and the risk stratification of patients with acute coronary syndromes.

Triage D-Dimer Test. An immunoassay for use as an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation or thromboembolic events, including pulmonary embolism and deep vein thrombosis.

Triage NT-proBNP Test. A fluorescence immunoassay to be used with the Triage® MeterPro for the quantitative determination of N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) in Ethylenediaminetetraacetic Acid (EDTA) anticoagulated whole blood and plasma specimens. The test is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is also used as an aid for the risk stratification of patients with heart failure and the risk stratification of patients with acute coronary syndromes (ACS).

Triage Troponin. Troponin I, T and C are protein subunits that make up the troponin complex, which is integral to the regulation of myofibril contraction in skeletal and cardiac muscle cells. Cardiac troponin I assays, for use with Quidel's Triage® MeterPro instrumented system, are commonly used as aids in the diagnosis of MI, which is injury to cardiac muscle cells caused by ischemia.

TriageTrue High Sensitivity Troponin. The TriageTrue High Sensitivity Troponin I Test is our latest generation of troponin assay used for the quantitative determination of troponin I in EDTA anticoagulated whole blood and plasma specimens, anticoagulated with EDTA, and features a redesigned cartridge that greatly improves assay sensitivity and precision that are critical to the performance of high sensitivity troponin testing. The test is to be used as an aid in the diagnosis of MI for use with Quidel's Triage MeterPro instrumented system.

Triage PLGF Test. An immunoassay for use as an aid in the early and accurate diagnosis of preterm pre-eclampsia in pregnant women.

Triage BNP Test for Beckman Analyzers. We also offer a version of our Triage BNP Test for use on Beckman Coulter lab analyzers.

Thyroid

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.

Autoimmune Thyroiditis. In 2017, we received the CE Mark for our Thyretain TBI Reporter BioAssay for the qualitative detection of blocking autoantibodies to the thyroid-stimulating hormone receptors (TSHR) in serum. The assay enables highly complex laboratories to diagnose autoimmune thyroiditis in just a few days, compared to traditional detection methods that could take months or even years.

Women's and General Health

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

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.

Group B Streptococcus (GBS). In 2017, we obtained FDA clearance of our Solana GBS Assay, used in conjunction with our Solana instrument, for the direct, qualitative detection of Group B Streptococcus from enriched broth cultures of specimens from antepartum women. GBS is commonly carried by pregnant women and can be transmitted to newborns at delivery, resulting in potential life-threatening illness. It is recommended that all pregnant women be tested for GBS during pregnancy.

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

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

Eye Health

Our InflammaDry and AdenoPlus products are rapid, lateral-flow based, POC products for the detection of infectious and inflammatory diseases and conditions of the eye. InflammaDry is a test that detects elevated levels of MMP-9, a key inflammatory marker for dry eye. AdenoPlus is a test that differentiates between a viral and bacterial infection of acute conjunctivitis (pink eye).

Gastrointestinal Diseases

Clostridium difficile. In 2017, we received FDA clearance of our Solana C. difficile Assay, used in conjunction with our Solana instrument, for the direct, qualitative detection of the Clostridium difficile DNA in unformed stool specimens of patients suspected of having Clostridium difficile-infection (CDI). In addition, we sell our Lyra Direct C. difficile Assay, a qualitative, multiplexed real-time PCR test for the detection of Clostridium difficile Toxin A or Toxin B genes approved for use on a variety of real-time PCR instruments, and our AmpliVue C. difficile Assay, which uses our HDA technology, for the detection of the Clostridium difficile Toxin A gene. Clostridium difficile can be a life threatening bacterial infection, especially for the elderly and patients on a prolonged antibiotic regimen.

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

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

Helicobacter pylori ("H. pylori"). H. pylori is the bacterium associated with patients diagnosed with peptic ulcers. H. pylori is implicated in chronic gastritis and is recognized by the World Health Organization as a Class 1 carcinogen

that may

10

increase a person's risk of developing stomach cancer. Our QuickVue rapid test is a serological test that measures antibodies circulating in the blood caused by the immune response to the H. pylori bacterium.

Toxicology

The toxicology testing market includes testing for substance use, misuse and abuse, including testing in connection with pain management and opioid cessation therapy. The ability to rapidly identify the impact of drug use on a patient's clinical presentation as well as securely monitor a patient's therapy compliance is critical to the substance abuse testing market. Our Triage TOX Drug Screen provides qualitative results for the determination of the presence of drug and/or the major metabolites in urine including assays for acetaminophen/paracetamol, amphetamines, methamphetamines, barbiturates, benzodiazepines, cocaine, methadone, opiates, phencyclidine, THC and tricyclic antidepressants.

Seasonality

Sales of our influenza 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 influenza 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, 2018, 2017 and 2016, sales of our influenza products accounted for 24%, 39% and 37%, respectively, of total revenue. This percentage decreased in 2018 in part as a result of the late 2017 acquisition of the Triage and BNP Businesses.

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 $51.6 million, $33.6 million, and $38.7 million for the years ended December 31, 2018, 2017 and 2016, respectively. We anticipate that we will continue to devote a significant amount of financial resources to product and technology research and development in the foreseeable future.

Marketing and Distribution

Our business strategy is designed around serving the continuum of healthcare delivery needs globally, starting with POC clinicians located in doctor's office practices, to moderately complex POLs, through the highly complex environment in hospital and clinical reference laboratories in North America and a variety of settings internationally. 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 and conditions. Our marketing strategy includes ensuring that our key product portfolios are supported by clinical validation and health economic and outcomes research that demonstrates to hospitals, laboratories, acute care facilities and POC clinicians that these tests deliver fast, high quality results, are cost-effective to use, and improve patient outcomes.

Our North America distribution strategy takes into account the fact that the POC market is highly fragmented, with many small or medium-sized customers. A network of national and regional distributors is employed, as well as our own sales force, to reach customers using POC diagnostic tests.

We have expanded the size of our North America sales force in the past few years. As of December 31, 2018, we employed more than 100 sales representatives in North America. This expanded sales force works closely with our key distributors to drive market penetration of our products in the POC market.

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

Internationally, we sell products in approximately 100 countries and market and distribute products in a variety of ways, including a mix of direct and distribution strategies worldwide. Certain markets remain on transition support services provided by Abbott Laboratories in connection with the Triage and BNP Businesses.

In Europe, we currently employ more than 65 employees, to support sales and marketing activities in key countries, such as Germany and Italy and intend to add more sales personnel to support the Triage and BNP Businesses. In addition, we have created a shared service center in Galway, Ireland to support general and administrative, technical support and customer service functions in Europe.

In Asia, we are focused on supporting the acquired Triage and BNP Businesses and continuing to grow our core immunoassay and cell culture businesses. We currently employ more than 40 employees in China, primarily to support sales and marketing efforts in China related to the acquired Triage and BNP Businesses. In addition, we are building out a shared service center in Shanghai, China to support general and administrative and technical support and customer service functions.

We derive a significant portion of our total revenue from a few distributors. Three of our distributors, which are considered to be among the market leaders, collectively accounted for approximately 44%, 54% and 44% of our total revenue for the years ended December 31, 2018, 2017 and 2016, respectively. See Note 9 “Industry and Geographic Information” and Note 12 “Acquisition” in the Consolidated Financial Statements included in this Annual Report.

Manufacturing

We have three primary manufacturing sites. Two are in San Diego, California and one is located in Athens, Ohio.

Our McKellar Court, Lateral Flow manufacturing facility is located in San Diego, and consists of laboratories devoted to tissue culture, cell culture, protein purification and immunochemistry. Production areas are dedicated to manufacturing and assembly. In the manufacturing process, biological and chemical supplies and equipment are used. We have invested in a high degree of automated inspection, assembly and testing. Since the year 2000, this facility has operated under a Quality Management System certified to International Organization for Standardization (“ISO”) standard. The facility is certified to ISO 13485:2016 and Medical Device Single Audit Program (“MDSAP”) as required for medical device manufacturers distributing product within the European Union (the “EU”) and other countries. Many of the immunoassay products manufactured in this San Diego facility are packaged and shipped by a local third party.

Our Athens facility consists of a molecular manufacturing laboratory dedicated to the manufacture and assembly of our molecular products, clean rooms (FS-209E Class 1000: ISO Class 6) for the culturing and dispensing of cell cultures under Good Manufacturing Practices (GMP) conditions and laboratories devoted to tissue culture for the production of monoclonal antibodies and the development and manufacture of research and MicroVue products. In the manufacturing process, biological and chemical supplies are used, as well as specialized equipment. The facility is certified to ISO 13485:2016 and MDSAP. Packaging and shipping logistics are handled at the facility.

Our Summers Ridge, San Diego facility consists of laboratories that are involved in mammalian cell culture, bacterial fermentation, protein purification and modification, as well as other techniques involved in immunoassay reagent manufacturing. These reagents are used in the manufacture of devices made at the site and are also supplied to a third party as key active ingredients for our BNP product that is run on the Beckman Coulter Immunoassay Systems. In addition, this site has production areas dedicated to creating and processing plastic components that are subsequently transformed into finished devices (Cardiac and Drugs of Abuse (“DOA”) products) using customized manufacturing equipment, including specialized automation. This facility is certified to ISO 13485:2003 / EN ISO 13485:2012 / (ISO 13485:2016 and MDSAP certification pending) medical device standards. Most of the products are packaged at this site and subsequently distributed by a third party.

We seek to conduct our manufacturing in compliance with regulations that comply to USA, Australia, Brazil, Canada, Japan, Europe, South Korea and other countries Quality Management System “QSR” requirements. Our manufacturing facilities have passed routine regulatory inspections confirming compliance with the QSR regulatory requirements. Our facilities are registered with various regulatory bodies including the USA FDA and the Department of Health Services of the State of California (the “State FDA”) for our San Diego facilities.

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 of diagnostic assays like our products 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, effectiveness or constitute a major change in the intended use of the device, will require new submissions to the FDA.

The FDA's current guidance entitled "Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 CLIA Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" sets forth requirements for obtaining a CLIA waiver that are onerous and have increased the time and cost required to obtain a CLIA waiver.

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

Regulation Outside of the United States

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

Our initial focus for obtaining marketing approval outside the U.S. is typically the European Union (the "EU"), Japan, China and Canada. EU Regulations and Directives generally classify healthcare products either as medicinal products, medical devices or in vitro diagnostics. The CE Mark certification for the EU requires us to receive ISO certification for the manufacture of our products. This certification comes only after the development of an all-inclusive quality system, which is reviewed for compliance with ISO standards by a notified body accredited by an EU member state. After certification is received, a technical file is developed which attests to the product's compliance with Regulation (EU) 2017/746 for in vitro diagnostic medical devices. Only after this point is the product CE marked. Japanese regulations require registration of in vitro diagnostic products with the Japanese Ministry of Health, Labor and Welfare. Chinese regulations require registration of diagnostic products with China's National Medical Products Administration (NMPA, formerly CFDA). Additional clinical trials are typically required for registration purposes.

For products marketed in Canada, registration is required with Health Canada and we have our independent party certification under the Canadian Medical Device Regulation.

Intellectual Property

The healthcare industry has traditionally placed considerable importance on obtaining and maintaining patent and trade secret protection for commercially relevant technologies, devices, products and processes. We and other companies engaged in

research and development of new diagnostic products actively pursue patents for technologies that are considered novel and patentable. However, important factors, many of which are not within our control, can affect whether and to what extent patent protection in the U.S. and in other important markets worldwide is obtained. By way of example, the speed, accuracy and consistency in application of the law in a patent office within any particular jurisdiction is beyond our control and can be unpredictable. The resolution of issues such as these and their effect upon our long-term success is likewise indeterminable. We have issued patents, both in the U.S. and internationally, with expiration dates ranging from the present through approximately 2036 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. Licenses may not be available to us at all or, if so available, may not be available on acceptable terms.

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

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

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

Competition

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

distributors since some have created, and others may decide to create, their own products to compete with ours. Competition may also be provided from large, medium and small development companies whose portfolio and technologies are dedicated to the development of diagnostic solutions in areas in which we currently have relevant market share.

Human Resources

As of December 31, 2018, we had 1,224 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 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, 61, was named President, Chief Executive Officer and a member of the Board of Directors in 2009. Prior to joining us, Mr. Bryant served as Executive Vice President and Chief Operating Officer at Luminex Corporation, managing its Bioscience Group, Luminex Molecular Diagnostics (Toronto), manufacturing, R&D, technical operations, and commercial operations. From 1983 to 2007, Mr. Bryant held various worldwide commercial operations positions with Abbott Laboratories including, among others: Vice President of Abbott Vascular for Asia/Japan, Vice President of Abbott Molecular Global Commercial Operations and Vice President of Abbott Diagnostics Global Commercial Operations. Earlier in his career with Abbott, Mr. Bryant was Vice President of Diagnostic Operations in Europe, the Middle East and Africa, and Vice President of Diagnostic Operations Asia Pacific. Mr. Bryant has over 30 years of industry experience in sales and marketing, product development, manufacturing and service and support in both the diagnostics and life sciences markets. Mr. Bryant holds a B.A. in Economics from the University of California at Davis.

Randall J. Steward, 64, became our Chief Financial Officer in October 2011. Prior to joining us, Mr. Steward served as the Chief Financial Officer for Navilyst Medical, Inc., a medical device company based in Massachusetts. From 2008 to January 2011, Mr. Steward served as Chief Operating Officer for SeQual Technologies, Inc., a San Diego-based medical device company, where he was responsible for all aspects of engineering, manufacturing, finance, and information systems. Prior to SeQual Technologies, Mr. Steward spent 11 years with Spectrum Brands as Executive Vice President and Chief Financial Officer. Mr. Steward holds a B.B.A. in Accounting from Southern Methodist University. He is also a Certified Public Accountant and a member of the American Institute of Certified Public Accountants.

Michael D. Abney, Jr., 55, became our Senior Vice President, Distribution in January 2015. Prior to joining us, he served as Vice President, Channel and Distribution for ConvaTec from 2013 to 2014 and held a number of positions at PSS World Medical, Inc. from 1989 to 2013, including most recently as Vice President, Supplier Management. Mr. Abney received his B.A. degree in Finance from the University of Florida in 1989.

Ratan S. Borkar, 45, became our Senior Vice President, International Commercial Operations in October 2017. He joined Quidel in May 2009 as Vice President, Business Development. In February 2012, Mr. Borkar moved into the role of VP, International Commercial Operations. Prior to Quidel, Mr. Borkar had a career in Investment Banking, where he most recently worked at J.P. Morgan as Vice President in the Healthcare Investment Banking Group, advising companies in the diagnostics, life sciences and clinical research areas. Mr. Borkar started his career at KPMG and is a Chartered Accountant. Mr. Borkar has an MBA from the University of Michigan’s Ross School of Business, where he was an Alan Gelband Scholar. Mr. Borkar received his Bachelor of Commerce from the University of Mumbai.

Robert J. Bujarski, J.D., 50, 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.

Karen C. Gibson, 57, became our Senior Vice President, Information Systems and Business Transformation in February 2019. She joined Quidel in April 2015 as Vice President, Information Systems and in 2017 took on additional responsibilities as the Integration Lead for the integration of the Triage and BNP Businesses. Prior to Quidel, Ms. Gibson was an independent executive consultant for approximately three years and previously held a

variety of senior positions within the life sciences industry. She held the role of Senior Vice President and Chief Information Officer for McKesson's Specialty Health division. She also served as Senior Vice President and Chief Information Officer for Life Technologies, and as Vice President and Chief Information Officer for General Electric's Healthcare IT business unit. Ms. Gibson has an MBA from Ohio University, and B.S. in Computer Technology from Purdue University.

Werner Kroll, Ph.D., 62, became our Senior Vice President, R&D in May 2014. Prior to joining us, Dr. Kroll was Vice President and Global Head Research and Innovation for Novartis Molecular since 2009. Prior to holding that position, he held a

variety of senior positions from 2005 to 2009 at Novartis. Dr. Kroll has also held senior positions at Bayer from 1991 to 2005. Dr. Kroll received his Ph.D. and a Diploma in Chemistry from the University of Marburg.

Edward K. Russell, 51, became our Senior Vice President, Global Commercial Operations in October 2015 and subsequently became our Senior Vice President, North America Commercial Operations. Prior to joining the Company, Mr. Russell was employed by Thermo Fisher Scientific, a life sciences company based in Massachusetts, and its predecessor company Life Technologies for ten years. Mr. Russell served in various leadership roles from 2005 through 2015, including North America Commercial Leader of the BioSciences Division, General Manager of Life Technologies' Global Services & Support Division, and President of Life Technologies Japan. Prior to joining Life Technologies in 2005, Mr. Russell held various leadership positions at FedEx Kinko's, ExxonMobil and Toyota/Lexus. Mr. Russell started his career as an officer in the U.S. Coast Guard. Mr. Russell holds a B.S. in Civil Engineering from the U.S. Coast Guard Academy and an MBA from The Wharton School, University of Pennsylvania.

Item 1A. Risk Factors

Risks Related to Our Business

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

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

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

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

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

To remain competitive, we must continue to develop, obtain and protect our proprietary technology rights; otherwise, we may lose market share or need to reduce prices as a result of competitors selling lower priced or 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, we may lose market share or need to reduce prices as a result of competitors selling lower priced or technologically superior products that compete with our products, and 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 2036. In addition to our patents in the U.S., we have patents issued in various other countries including, among others, Australia, Canada, Japan, various European countries, including France, Germany, Italy, Spain and the United Kingdom, and South Africa. 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 proprietary technology 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 could 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, there will be no assurance that 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 and new technologies 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 significant operating expenses as a result of continued investment in sales and marketing activities, manufacturing scale-up and new product development associated with our efforts to accomplish our business strategies discussed in "Business - Business Strategy" in Part I of this Annual Report. No assurance can be given that we will be successful in implementing our operational, growth and other strategic efforts. In addition, the funds for our strategic development projects have in the past come primarily from our business operations, borrowings under available lines of credit and the sale of equity and debt securities. If our business slows and we become less profitable, and as a result we 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.

18

Our operating results are heavily dependent on sales of our influenza diagnostic tests and if sales or revenues of our influenza tests decline for any reason, our operating results would be materially and adversely affected on a disproportionate basis.

Although we continue to diversify our products, a significant percentage of our total revenues still continue to come from a limited number of our product families. In particular, revenues from the sale of our influenza tests represent a significant portion of our total revenues and are expected to remain so for at least the near future. In addition, the gross margins derived from sales of our influenza tests are significantly higher than the gross margins from many of our other core products. As a result, if sales or revenues of our influenza tests decline for any reason whether as a result of a mild flu season, market share loss or price pressure, obsolescence, 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, 2018, 2017 and 2016, sales of our influenza products accounted for 24%, 39%, and 37% respectively, of total revenue.

We rely on a limited number of key distributors that account for a significant portion of our total revenue. The loss of any key distributor or an unsuccessful effort by us to directly distribute our products could lead to reduced sales.

Although we have many distributor relationships in the U.S., the market is dominated by a small number of these distributors. Three of our distributors, which are considered to be among the market leaders, collectively accounted (each individually in excess of 10%) for approximately 44%, 54%, and 44% of our total revenue for the years ended December 31, 2018, 2017 and 2016, respectively. In addition, we rely on a few key distributors for a majority of our international sales and expect to continue to do so for the foreseeable future. The loss or termination of our relationship with any of these key distributors could significantly disrupt our business unless suitable alternatives are timely found or lost sales to a 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 from a lost or terminated distributor to one or more new distributors, our business, operating results and financial condition could be materially and adversely affected.

We are subject to, and may in the future become subject to, claims and litigation that could result in significant expenses and could ultimately result in an unfavorable outcome for us.

From time to time, we are involved in litigation and other proceedings, including matters related to product liability claims, commercial disputes and intellectual property claims, as well as regulatory, employment, and other claims related to our business. Litigation related to our company, our business, and its operations or financial performance may also involve customers, competitors, suppliers, patients, shareholders, governmental authorities or other third parties. Litigation can be lengthy, expensive and disruptive to our operations, and results cannot be predicted with certainty. An adverse decision could result in significant settlement amounts, monetary damages, fines or injunctive relief that could affect our financial condition or results of operations. Even if lawsuits do not result in an unfavorable outcome, the costs of defending or prosecuting such lawsuits may be material to our business and our operations. Moreover, these lawsuits may divert management's attention from the operation of our business, which could adversely affect our business and results of operations.

For example, as further described in Note 8 to the Consolidated Financial Statements contained in Part II, Item 8 of this Annual Report, Beckman Coulter, Inc. ("Beckman") filed a lawsuit against us in November 2017. The lawsuit relates to a contractual arrangement with Beckman we acquired in October 2017 as part of the BNP Business for the supply of antibodies and other inputs related to, and distribution of, the Triage® BNP Test for the Beckman Coulter Access Family of Immunoassay Systems. The outcome of such lawsuit may affect the value of the assets and liabilities we acquired and expose us to monetary liability. While we believe that the claims in the lawsuit are without merit, we can provide no assurance that we will be successful in defending the claims. If this lawsuit, or any other lawsuit filed against us, is resolved against us, we may be liable for significant damages and restraints on our business, which could adversely affect our results of operations and financial condition.

Moreover, the deferred consideration we are required to pay Alere for the BNP Business will be payable even if BNP sales are significantly reduced, or even terminate, including because of a determination that provisions of the contractual arrangement with Beckman are unenforceable, in which case such payment obligations may significantly exceed the income we generate from the BNP Business. In addition, if the contractual arrangement with Beckman is determined to be unenforceable, it could result in a reduction or impairment of all or a part of the value of the goodwill and intangible assets we recorded in connection with our acquisition of the BNP Business.

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. In developing and producing new products and entering new markets, 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. Moreover, we are and have been subject to litigation with parties that claim, among other matters, that we infringed their patents or other intellectual property 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.

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:

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

Even if licenses to intellectual property rights are available, they can be costly. We have entered into various licensing agreements, which largely require payments based on specified product sales and/or the achievement of specific milestones. Royalty and license expenses under these arrangements collectively totaled $0.4 million, $0.6 million and $0.8 million for the years ended December 31, 2018, 2017 and 2016, respectively.

In addition to the foregoing, we may also be required to indemnify certain customers, distributors and strategic partners under our agreements with such parties if a third party alleges or if a court finds that our products or activities

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

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

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

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

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

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. 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 competitive advantages, such as 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. Our operating results could be materially and adversely affected if:

- our competitors' products are more effective than ours or take market share from our products through more effective marketing or competitive pricing;
- our competitors obtain patent protection or other intellectual property rights that prevent us from offering competing products or services; or
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our competitors are able to obtain regulatory approvals for products or services or otherwise bring competing products to market earlier than us.

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 to 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 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 or clearances 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. Similarly, conducting clinical studies that may be required for regulatory approvals or clearances is a complex, time-consuming and expensive process, requiring months or years to complete, and our studies are not guaranteed to generate data that demonstrate safety and effectiveness or substantial equivalence of the evaluated product.

In addition, even after we obtain necessary clearances or approvals to market our products, the FDA and other regulatory agencies may require post-market testing and additional surveillance to monitor the performance and use of approved products or may place conditions on any product approvals that could restrict the commercial applications of those products. Our results of operations would be negatively affected by failures or delays in the receipt of regulatory approvals or clearances, changes in laws and regulations, the loss of previously received approvals or clearances or the placement of limits on the manufacture, marketing and use of our products. For example, prior to our acquisition of the Triage Business, the Summers Ridge, San Diego facility was subject to a 2012 FDA inspection that resulted in recalls of Triage products and revised release specifications for certain Triage meter-based products, which will not be formally been closed-out with the FDA until after a future inspection. We cannot assure you that the government will find efforts to resolve the FDA warning letter to be satisfactory. We cannot predict whether other governments' regulatory authorities will require additional remedial or corrective actions in the future, and the issues arising out of the FDA inspection may be expanded to cover other matters.

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 recalls, seizures or injunctions with respect to the sale of our products. The assessment of any civil and criminal penalties against us could severely impair our reputation within the industry and affect our operating results, and any limitation on our ability to manufacture and market our products could also have a material adverse effect on our business.

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

Changes in government policy could have a significant impact on our business by increasing the cost of doing business, affecting our ability to sell our products and negatively impacting our profitability. Such changes could include modifications to existing legislation, such as U.S. tax policy, or entirely new legislation, such as the Affordable Healthcare Act ("AHA") in the U.S. Although we cannot fully predict the many ways that healthcare reform might affect our business, the AHA imposed a 2.3% medical device excise tax ("MDET") on certain transactions, including many U.S. sales of medical devices, which includes the majority of our U.S. product sales. This tax took effect January 1, 2013. For the year ended December 31, 2015, we incurred $2.1 million related to the MDET, and although the MDET was suspended for 2016, 2017 and a two-year moratorium was recently implemented for 2018 and 2019, it may be reinstated. It is unclear whether and to what extent, if at all, other anticipated developments, including changes due to governmental administrative priorities, or changes resulting from healthcare reform, such as a change in the number of people with health insurance, may impact us.

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

In addition to FDA and other regulations referred to above, numerous laws relating to such matters as safe working conditions, manufacturing practices, employment practices, data privacy, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances impact our business or operations. If these laws or their

interpretation change or new laws regulating any of our businesses or operations are adopted, the costs of compliance with these laws could substantially increase our overall costs. Failure to comply with any laws, including laws regulating the manufacture and marketing of our products, could result in substantial costs and loss of sales or customers. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our operations, it is impossible to reliably predict the full nature and impact of future legislation or regulatory developments relating to our industry and our products. To the extent the costs and procedures associated with meeting new or changing requirements are substantial, our business, results of operations and financial condition could be adversely affected.

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

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

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

The end-users of our products are primarily physicians and other healthcare providers. In the U.S., healthcare providers such as hospitals and physicians who purchase diagnostic products generally rely on third-party payers, principally private health insurance plans, federal Medicare and state Medicaid, to reimburse all or part of the cost of the procedure. Use of our products would be adversely impacted if physicians and other healthcare providers do not receive adequate reimbursement for the cost of our products by their patients' third-party payers. Our total revenue could also be adversely affected by changes or trends in reimbursement policies of these governmental or private healthcare payers. We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the U.S. in recent years, currently available levels of reimbursement may not continue to be available in the future for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the U.S. or foreign markets, current reimbursement amounts may be decreased in the future and future legislation, regulation or reimbursement policies of third-party payers may reduce the demand for our products or adversely impact our ability to sell our products on a profitable basis.

Billing and payment for healthcare services are highly regulated, and the failure to comply with applicable laws and regulations can result in civil or criminal sanctions, including exclusion from federal and state healthcare programs.

A portion of our healthcare products and services are paid for by private and governmental third-party payers, such as Medicare and Medicaid. These third-party payers typically have different and complex billing and documentation requirements that we must satisfy in order to receive payment, and they carefully audit and monitor our compliance with these requirements. Such audits may lead to determinations that certain claims should not have been paid, and payors may seek to recoup or offset amounts they assert have been paid in error.

We must also comply with numerous other laws applicable to billing and payment for healthcare services, including privacy laws. Failure to comply with these requirements may result in non-payment, refunds, exclusion from government healthcare programs and civil or criminal liabilities, any of which may have a material adverse effect on our revenues, earnings
and cash flows. In addition, failure by third-party payers to properly process our payment claims in a timely manner could delay our receipt of payment for our products and services, which may have a material adverse effect on our cash flows.

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 or supply shortfalls, 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, reputation, operating results and financial condition.

Unexpected increases in demand for our products or supply shortfalls 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 or supply shortfall, particularly those obtained from a sole supplier or a limited group of suppliers.

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

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

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

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

Our business involves an inherent risk of product liability claims. Our product development and production processes are complex and could expose our products to claims of defectiveness. Alleged manufacturing and design defects could lead to recalls (either voluntary or required by the FDA or other government authorities) and could result in the removal of one or more of our products from the market. Similarly, a defect in one of our diagnostic products could lead to a false positive or false negative result, affecting the eventual diagnosis or treatment. Any such defects may require the payment of significant amounts in damages in connection with lawsuits. A defect or claim of a defect in the design or manufacture of our products could also have a material adverse effect on our reputation in the industry. Moreover, any product liability or other claim brought against us, regardless of merit, could be costly to defend.

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

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

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

We utilize complex information technology systems to support our business and process, transmit, and store information, including sensitive personal information and proprietary or confidential information. We cannot be sure that our systems will meet our future business needs or that necessary upgrades will operate as designed, which could result in excessive costs or disruptions in portions of our business. In particular, any disruptions, delays or deficiencies caused by our enterprise resource planning system could adversely affect our ability to process orders, ship products, provide services and customer support, send

invoices and track payments, fulfill contractual obligations or otherwise operate our business. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, could result in a material disruption in our operations.

Our ability to protect our information systems and electronic transmissions of sensitive data from data corruption, cyber-based attacks, security breaches or privacy violations is critical to the success of our business.

Although we invest in security technology designed to protect our data against data security breaches and cyber-attacks, and we have implemented solutions, processes and procedures to help mitigate these risks at various locations, such as encryption, virus protection, security firewalls and information security and privacy policies, our information technology and infrastructure are subject to attacks or misappropriation by hackers and may be breached due to inadequacy or ineffectiveness of the protective measures undertaken, employee errors or omissions, malfeasance or other disruptions. A security breach or privacy violation that leads to disclosure of consumer, customer, supplier, partner or employee information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state and foreign breach notification laws and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue.

Despite our efforts to protect against cyber-attacks and security breaches, hackers and other cyber criminals are using increasingly sophisticated and constantly evolving techniques, and we may need to expend substantial additional resources to continue to protect against potential security breaches or to address problems caused by such attacks or any breach of our safeguards. In addition, a data security breach could distract management or other key personnel from performing their primary operational duties.

The interpretation and application of consumer and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. Among other things, foreign privacy laws impose significant obligations on U.S. companies to protect the personal information of foreign citizens. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data practices, which could have a material adverse effect on our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to 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. In addition, the loss of any of our key personnel, particularly key technical and research and development personnel, could harm our business and prospects and could impede the achievement of our research and development, operation or strategic objectives.

We face risks relating to our international sales, including inherent economic, political and regulatory risks, that 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 direct sales, distributor organizations and sales agents. Sales to foreign customers accounted for 32%, 18% and 17% of our total revenue for the years ended December 31, 2018, 2017 and 2016, respectively. Our international operations 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 product 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 and enforcing agreements with foreign entities;
- reduced, or lack of, protection for, and enforcement of, intellectual property rights;
- social, political and economic instability in some of the regions where we currently sell our products or that we may expand into in the future;
- increased financial accounting and reporting burdens and complexities;
- complex and potentially adverse tax consequences; and
- diversion to the U.S. of our products sold into international markets at lower prices.

Our international operations are governed by the U.S. Foreign Corrupt Practices Act and similar anti-corruption laws outside the U.S. Global enforcement of anti-corruption laws has increased substantially in recent years, with more enforcement proceedings by U.S. and foreign governmental agencies and the imposition of significant fines and penalties. While we have implemented policies and procedures to comply with these laws, our international operations, which may involve customer relationships with foreign governments, create the risk that there may be unauthorized payments or offers of payments made by employees, consultants, sales agents or distributors. Any alleged or actual violations of these laws may subject us to government investigations, significant criminal or civil sanctions and other liabilities, and negatively affect our reputation.

During the year ended December 31, 2018, we generated approximately $142.3 million in revenue denominated in currencies other than the U.S. dollar. The major currencies to which our revenues are exposed are the Euro and the Chinese Yuan. Continued change in the values of the Euro, the Chinese Renminbi, and other foreign currencies could have a negative impact on our business, financial condition and results of operations.

Beginning in 2019, the Company has initiated a foreign currency management policy which permits the use of derivative instruments, such as forward contracts, to reduce volatility in our results of operations resulting from foreign exchange rate fluctuations. We do not enter into foreign currency derivative instruments for trading purposes or to engage in speculative activity. 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.

Changes in our tax rates or exposure to additional income tax liabilities or assessments could affect our profitability.

We are subject to income taxes in the U.S. and in various non-U.S. jurisdictions. In addition, the amount of income taxes we pay is subject to ongoing audits by U.S. federal, state and local tax authorities and by non-U.S. tax authorities. Due to the potential for changes to tax laws (or changes to the interpretation thereof) and the ambiguity of tax laws, the subjectivity of factual interpretations, the complexity of our foreign operations and intercompany arrangements and other factors, our estimates of income tax assets or liabilities may differ from actual payments, assessments or receipts. If these audits result in payments or assessments different from our reserves, our future results may include unfavorable adjustments to our tax liabilities and our financial statements could be adversely affected. If we determine to repatriate earnings from foreign jurisdictions that have been considered permanently re-invested under existing accounting standards, it could also increase our effective tax rate. In addition, any significant change to the tax system in the United States or in other jurisdictions (including changes in the taxation of international income as further described below) could adversely affect our financial statements.

Risks Related to Our Acquisitions

Our acquisition of Alere’s Triage® and BNP Businesses presents certain risks to our business and operations

On October 6, 2017, we acquired the Triage and BNP Businesses from Alere. See Note 12 to the Consolidated Financial Statements contained in Part II, Item 8 in this Annual Report for additional information concerning these acquisitions. The acquisition of these businesses, and the transition and integration process related thereto, present certain risks to our business and operations, including, among other things, risks that:

- we may be unable to successfully transition and integrate the businesses, and we may experience business interruptions during transition and integration;
-

we may not realize the anticipated benefits of the acquisitions, including those anticipated to arise from reducing costs, making product and process improvements and developing new products;

- we may lose management personnel and other key employees and be unable to attract and retain personnel and employees;

- management's attention and our other resources may be focused on integration activities instead of on day-to-day management activities, including pursuing other beneficial opportunities;
- we may incur substantial unexpected integration or transition related costs;
- the deferred consideration payable to Alere for the BNP Business will be payable even if BNP sales are significantly reduced, or even terminate, whether as a result of the introduction of a competing product, a determination that provisions of the contractual arrangement with Beckman are unenforceable or otherwise, and such payment obligations may significantly exceed the revenues from such business;
- we may not be able to successfully or efficiently manage our foreign expansion, and the acquired businesses will increase our exposure and risks related to foreign markets;
- we may be subject to claims, litigation, other legal proceedings and liabilities and damages in connection with the businesses and assets acquired in the acquisitions, some of which may not be covered in full, if at all, by the indemnification provisions provided for in the acquisition agreements, and even if indemnified, may be disruptive to our business;
- we may not be able to receive required regulatory approvals or clearances relating to the acquired businesses and the acquired products, or may lose previously received regulatory approvals or clearances;
- in certain international markets, the marketing authorizations to sell the acquired products are being held by Alere post-closing until the authorizations can be transferred to us through the applicable regulatory process, and such deferred transfers have additional risks, including:
- we may not timely receive such authorizations, if at all, or may encounter unexpected difficulties and costs in receiving the authorizations;
- we may have less control over the acquired businesses until the deferred transfers occur;
- completion of the acquisitions may trigger assignment or other provisions in certain commercial contracts to which Alere was a party, such that counterparties may potentially have the right to terminate the contracts; and
- launching branding or rebranding initiatives may involve substantial costs and may not be favorably received by customers.

Alere may fail to perform under various transition agreements that were entered into as part of our acquisition of the Triage and BNP Businesses and we may fail to have necessary systems and services in place when certain of the transition services expire.

In connection with the acquisition of the Triage and BNP Businesses, we entered into a number of agreements with Alere, including transition services agreements and a manufacturing and supply agreement. Certain of these agreements will provide for the performance of services by each company for the benefit of the other for a period of time after the closing of the acquisitions of the Triage and BNP Businesses. If Alere is unable or unwilling to satisfy its payment or performance obligations under these agreements, we could incur operational difficulties or losses which could have a material adverse effect on our profitability and business. In addition, if the costs that we must pay for the services under these agreements significantly increase this could affect our profitability. Moreover, if we do not have our own systems and services in place, or if we do not have agreements in place with other providers of these services when the term of a particular transition service terminates (whether at the end of the term or as a result of an early termination), we may not be able to operate our business effectively, and the cost of such systems and services may be greater than what is provided under the transition services.

As we build our information technology infrastructure and transition the Triage and BNP Businesses to our own systems, we could incur substantial additional costs and experience temporary business interruptions.

We continue to install and implement information technology infrastructure to support critical business functions relating to the Triage and BNP Businesses, including accounting and reporting, customer service, inventory control and distribution, billing and receivables collection, as well as order entry, warehousing and other administrative services. Under the transition services agreements with Alere, Alere is required to provide services both inside and outside the United States, including back office services, for up to two years following the closings of the acquisitions of the Triage and BNP Businesses. The services provided include information technology, billing and receivables collection, as well as order entry, warehousing, and certain other administrative services. These transition services agreements allow us to operate the Triage and BNP Businesses prior to establishing our back-office infrastructure and

information technology systems to accommodate the Triage and BNP Businesses. Our failure to avoid operational interruptions as we implement the new systems and information technology could disrupt our integration of the Triage and BNP Businesses and have a material adverse effect on our profitability.

If goodwill or other intangible assets that we have recorded in connection with our acquisitions of other businesses become impaired, we may be required to take significant charges against earnings.

As a result of our acquisitions, we have recorded, and may continue to record, a significant amount of goodwill and other intangible assets. Under current accounting standards, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other intangible assets has been impaired. Any reduction or impairment of the value of goodwill or other intangible assets will result in additional charges against earnings, which could materially reduce our reported results of operations in future periods.

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 we expect 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 successfully identify and acquire attractive targets. Other risks associated with acquiring other technologies or businesses, include: inability to obtain financing for acquisitions on satisfactory terms or at all; difficulties integrating the operations of companies or technologies that we acquire with our own operations; diversion of the attention of management and key personnel from our core business; adverse effects on our existing business relationships; potential loss of key employees of the acquired businesses; write-downs of goodwill, intangible assets or other assets associated with the acquisitions; and we may not realize our anticipated benefits and cost savings within our expected time frame, or at all, or may experience unexpected costs. 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.

Risk Factors Related to our Indebtedness and Other Obligations

Our debt and deferred payment obligations could materially adversely affect our financial condition and results of operations.

We have outstanding indebtedness under our Revolving Credit Facility and Convertible Senior Notes described in Note 3 to the Consolidated Financial Statements included in Part II, Item 8 of this Annual Report, and may incur other indebtedness from time to time. We also have significant deferred and contingent payment obligations to Alere for the BNP Business described in Note 12 to the Consolidated Financial Statements included in Part II, Item 8 of this Annual Report.

The degree to which we are leveraged and are subject to deferred payment obligations could have important consequences to our business and operating results, including:

- our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions and general corporate purposes may be impaired;
- a significant portion of our cash flow from operating activities must be dedicated to the payment of our debt, which reduces the funds available to us for our operations and may limit our ability to engage in acts that may be in our long-term best interests;
- some of our debt is and will continue to be at variable rates of interest, which may result in higher interest expense in the event of increases in market interest rates;
- our debt agreements contain, and any agreements to refinance our debt likely will contain, financial and other restrictive covenants, and our failure to comply with them may result in an event of default, which, if not cured or waived, could have a material adverse effect on us;
- our level of indebtedness and deferred payment obligations may increase our vulnerability to, and reduce our flexibility to respond to, general economic downturns and adverse industry and business conditions;
- as our long-term debt ages, we may need to renegotiate or repay such debt or seek additional financing;

- to the extent the debt we incur requires collateral to secure such indebtedness, our assets could be at risk and our flexibility related to such assets could be limited; and
- our debt service and deferred payment obligations could limit our flexibility in planning for, or reacting to, changes in our business and industry.

We may not be able to generate sufficient cash flow to meet our debt service and deferred and contingent payment obligations, and any inability to repay our debt when due would have a material adverse effect on our business, financial condition and results of operations.

Our ability to generate sufficient cash flow from operating activities to make scheduled or other required payments on our debt obligations, deferred payment obligations and maintain a desired level of capital expenditures depends on our future performance, which is subject to economic, financial, competitive and other factors, many of which are beyond our control. 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 undertake these activities may also be restricted by the terms of our various debt instruments then in effect. In addition, our ability to refinance our indebtedness or issue additional equity capital 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. Any such default on our debt obligations could materially adversely affect our business, financial condition and results of operations.

The Revolving Credit Facility is secured by substantially all of our assets and those of our subsidiary guarantors.

Borrowings under the Amended and Restated Credit Agreement are guaranteed by certain of our material domestic subsidiaries and are secured by liens on substantially all of our assets and those of the guarantor subsidiaries, other than real property and certain other types of excluded assets. If we default under our secured indebtedness, including our Revolving Credit Facility, the holders of such debt could proceed against the collateral securing that indebtedness, which could materially adversely affect our business, financial condition and results of operations.

The agreements relating to our indebtedness contain terms that restrict our ability to operate our business, and as a result, may materially and adversely affect our results of operations.

Our Revolving Credit Facility contains, and other of our debt agreements may include from time to time, a number of restrictive covenants that impose significant operating and financial restrictions on us and our subsidiaries. Such restrictive covenants significantly limit our ability to:

- incur additional debt, including guarantees;
- allow other liens on our property;
- make certain investments and acquisitions;
- sell or otherwise dispose of assets;
- engage in mergers or consolidations or allow a change in control to occur;
- make distributions to our stockholders;
- engage in restructuring activities;
- enter into transaction with affiliates;
- prepay or amend other indebtedness;
- engage in certain sale and leaseback transactions; and
- issue or repurchase stock or other securities.

Such agreements also require us to satisfy other requirements, including maintaining certain financial ratios. Our ability to meet these requirements can be affected by events beyond our control and we may be unable to meet them. To the extent we fail to meet any such requirements and are in default under our debt obligations, our financial condition may be materially adversely affected. These restrictions may also limit our ability to engage in activities that could otherwise benefit us. To the extent that we are unable to engage in activities that support the growth, profitability and competitiveness of our business, our results of operations may be materially adversely affected.

An event of default under any agreement relating to our outstanding indebtedness or other event that could require outstanding debt to be prepaid or purchased by us could cross default other indebtedness, which could have a material adverse effect on our business, financial condition and results of operations.

If there were an event of default under any of the agreements relating to our outstanding indebtedness, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately, which default or acceleration of debt could cross default other indebtedness. Our Revolving Credit Facility could also be cross defaulted as a result of other events that could require us to prepay or purchase outstanding indebtedness. Any cross default with respect to any of our indebtedness would put immediate pressure on our liquidity and financial

condition and would amplify the risks described above with regards to being unable to repay our indebtedness when due and payable. We cannot assure you that our

assets or cash flow would be sufficient to fully repay borrowings under our outstanding debt instruments if accelerated upon an event of default, and, as described above, any inability to repay our debt when due could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

If interest rates increase, our debt service obligations under our variable rate indebtedness could increase significantly, which could have a material adverse effect on our results of operations.

Borrowings under certain of our facilities from time to time, including under our Revolving Credit Facility, are at variable rates of interest and as a result expose us to interest rate risk. If interest rates were to increase, our debt service obligations on the variable rate indebtedness would increase even though the amount borrowed remained the same, and our net income and cash flows will correspondingly decrease. To the extent the risk materializes and is not fully mitigated, the resulting increase in interest expense could have a material adverse effect on our results of operations.

Risks Related to our Common Stock

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, we may issue shares of our common stock or securities convertible into our common stock from time to time in connection with a debt refinancing or replacement, acquisition, or other transaction. 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;
- adverse litigation developments;
- developments or disputes relating to patents or proprietary rights;
- failure to meet the expectations of stock market analysts and investors;
- changes in stock market analyst recommendations regarding our common stock;
- changes in healthcare policy in the U.S. or other countries; and
- general stock market conditions and other factors unrelated to our operating performance.

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 our stockholders' 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 at least 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 us that would otherwise be beneficial to investors.

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

At December 31, 2018, we occupied the indicated square footage in the leased and owned facilities described below:

Location	Status	Lease term	Square Footage	Primary Use
San Diego, CA (McKellar)	Leased	2020 - options to extend for three additional 5-year periods	78,000	Administrative offices, research and development and manufacturing
San Diego, CA (High Bluff)	Leased	2022 - options to extend for two additional 5-year periods	30,000	Administrative offices, sales and marketing (principal executive offices)
San Diego, CA (Summers Ridge)	Leased (1)	2033 - options to extend for two additional 5-year periods	192,000	Administrative offices, research and development and manufacturing
Athens, OH	Leased	2022 - option to extend for one additional 5-year period	94,000	Administrative offices, sales and marketing, research and development and manufacturing
Beverly, MA	Leased (2)	2020 - option to extend for one additional 5-year period	9,700	Administrative offices, research and development and manufacturing
Shanghai, China	Leased	2021 - option to extend for one additional 2-year period	8,500	Administrative offices, sales and marketing
Galway, Ireland	Leased	2028	3,900	Administrative offices, sales and marketing

(1) The Summers Ridge lease is subject to certain must-take provisions related to two additional buildings, consisting of approximately 125,000 square feet. See Note 8 in the Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

(2) In January 2019, the Company entered into an agreement to extend the Beverly, MA lease through October 2023, which provides for three-year automatic extensions unless notice to terminate is given by either party six months in advance.

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

The information set forth in “Litigation and Other Legal Proceedings” in Note 8 in the Consolidated Financial Statements in Part II, Item 8 of this Annual Report is incorporated herein by reference.

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."

As of February 8, 2019, we had approximately 331 common stockholders of record and we do not anticipate paying any cash dividends in the foreseeable future.

Issuer Purchases of Equity Securities

During the year ended December 31, 2018, 89,747 shares of outstanding common stock with a value of $4.3 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 units ("RSUs"). These shares are not considered repurchases under the Company's prior share repurchase programs.

The table below sets forth information regarding repurchases of our common stock by us during the three months ended December 31, 2018:

Period	Total number of shares purchased (1)	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Approximate dollar value of shares that may yet be purchased under the plans or programs (2)
October 1, 2018 - October 28, 2018	3,763	$ 63.28	—	$—
October 29, 2018 - November 25, 2018	4,737	66.68	—	—
November 26, 2018 - December 30, 2018	—	—	—	50,000,000
Total	8,500	$ 65.38	—	$ 50,000,000

(1) We withheld 8,500 shares of common stock from employees in connection with payment of minimum tax withholding obligations relating to the lapse of restrictions on certain RSUs during the three months ended December 31, 2018.

(2) On December 12, 2018, the Board of Directors authorized a new stock repurchase program, pursuant to which up to $50.0 million of the Company's shares of common stock may be purchased through December 12, 2020. The Company announced the stock repurchase program on December 18, 2018.

STOCKHOLDER RETURN PERFORMANCE GRAPH

Set forth below is a line graph comparing the yearly percentage change in the cumulative total stockholder return on our common stock with the cumulative total return of the Nasdaq Composite Index, Nasdaq Health Care Index, and Nasdaq US Benchmark Medical Supplies Index for the period beginning December 31, 2013 and ending December 31, 2018. The graph assumes (i) an initial investment of $100 on December 31, 2013 in our common stock, the Nasdaq Composite Index, the Nasdaq US Benchmark Medical Supplies Index, and the Nasdaq Health Care Index and (ii) reinvestment of dividends. The stock price performance of our common stock depicted in the graph represents past performance only and is not necessarily indicative of future performance.

COMPARISON OF 5 YEAR TOTAL CUMULATIVE RETURN

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

	Base Period					
Company/Index	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
Quidel Corporation	$ 100.00	$ 93.62	$ 68.63	$ 69.34	$ 140.34	$ 158.04
NASDAQ Composite	$ 100.00	$ 113.40	$ 119.89	$ 128.89	$ 165.29	$ 158.87
NASDAQ US Benchmark Medical Supplies	$ 100.00	$ 118.72	$ 130.08	$ 147.04	$ 191.95	$ 181.86
NASDAQ Health Care	$ 100.00	$ 128.47	$ 137.28	$ 114.06	$ 138.36	$ 132.59

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,				
	2018	2017 (1)	2016 (1)	2015	2014
	(in thousands, except per share data)				
Total revenues	$522,285	$277,743	$191,603	$196,129	$184,158
Cost of sales	206,572	121,601	79,872	78,029	80,463
Gross profit	315,713	156,142	111,731	118,100	103,695
Research and development	51,649	33,644	38,672	35,514	37,913
Sales and marketing	108,987	67,248	50,436	50,401	45,621
General and administrative	44,951	29,192	26,351	27,057	25,811
Acquisition and integration costs	14,197	16,506	711	2,390	—
Impairment loss	—	—	—	—	3,558
Total operating expenses	219,784	146,590	116,170	115,362	112,903
Operating income (loss)	95,929	9,552	(4,439)	2,738	(9,208)
Other expense, net					
Interest expense, net	(24,283)	(17,588)	(12,181)	(12,035)	(1,775)
(Loss) gain on extinguishment of debt	(8,262)	—	421	—	—
Total other expense, net	(32,545)	(17,588)	(11,760)	(12,035)	(1,775)
Income (loss) before income taxes	63,384	(8,036)	(16,199)	(9,297)	(10,983)
(Benefit) provision for income taxes	(10,799)	129	(2,391)	(3,218)	(3,909)
Net income (loss)	$74,183	$(8,165)	$(13,808)	$(6,079)	$(7,074)
Basic earnings (loss) per share	$1.95	$(0.24)	$(0.42)	$(0.18)	$(0.21)
Diluted earnings (loss) per share	$1.86	$(0.24)	$(0.42)	$(0.18)	$(0.21)
Shares used in basic per share calculation	37,995	33,734	32,708	34,104	34,451
Shares used in diluted per share calculation	42,554	33,734	32,708	34,104	34,451

Balance Sheet Data

	December 31,				
	2018	2017 (1)	2016 (1)	2015	2014
	(in thousands)				
Cash and cash equivalents	$43,695	$36,086	$169,508	$191,471	$200,895
Working capital	$33,662	$202,881	$191,782	$209,834	$238,096
Adjusted working capital (2)	$88,041	$202,881	$191,782	$209,834	$238,096
Total assets	$806,371	$935,251	$388,250	$406,505	$447,411
Long-term debt and lease obligation, net of current portions	$56,865	$381,110	$148,319	$147,329	$142,575
Stockholders' equity	$425,584	$227,104	$200,630	$218,676	$245,011
Common shares outstanding	39,386	34,540	32,897	33,323	34,433

(1) Includes the results of operations of the Immutopics, Inc., RPS Diagnostics and Triage and BNP Businesses, from dates of acquisition, March 18, 2016, May 16, 2017 and October 6, 2017, respectively.

(2) Adjusted working capital as of December 31, 2018 excludes the current portion of the Convertible Senior Notes of $54.4 million as such notes may be settled at the Company's option in cash or a combination of cash and shares of common stock.

35

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 3 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 rapid diagnostic testing solutions. These diagnostic testing solutions are separated into our four product categories: rapid immunoassays, cardiac immunoassays, specialized diagnostic solutions and molecular diagnostic solutions. We sell our products directly to end users and distributors, in each case, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, urgent care clinics, leading universities, retail clinics, pharmacies and wellness screening centers. We market our products through a network of distributors and through a direct sales force. The Company operates in one business segment that develops, manufactures and markets our four product categories.

For the year ended December 31, 2018, total revenue increased 88% to $522.3 million as compared to the year ended December 31, 2017 primarily due to the acquisition of the Triage and BNP Businesses from Alere on October 6, 2017, which represented 51% of our total revenues for the year ended December 31, 2018. See further discussion in Note 12 in the Consolidated Financial Statements in Part II, Item 8 of this Annual Report. For the years ended December 31, 2018, 2017 and 2016, sales of our influenza products accounted for 24%, 39%, and 37% respectively, of total revenue. Additionally, a significant portion of our total revenue is from a relatively small number of distributors. Approximately 44%, 54% and 44% of our total revenue for the years ended December 31, 2018, 2017 and 2016, respectively, were related to sales through our three largest distributors.

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

- rapid immunoassay tests for use in physician offices, hospital laboratories and emergency departments, retail clinics, eye health settings, pharmacies and other urgent care or alternative site settings;
- cardiac immunoassay tests for use in physician offices, hospital laboratories and emergency departments, and other urgent care or alternative site settings;
- specialized diagnostic solutions, including DFA and culture-based tests for the clinical virology laboratory and other products serving the bone health, autoimmune and complement research communities; and
- molecular diagnostic tests for use in hospitals, moderately complex physician offices, laboratories and other settings.

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

- leveraging our current infrastructure to develop and launch new Rapid Immunoassays and Cardiac Immunoassays such as additional assays for our Sofia® and Sofia® 2 analyzers and Triage® MeterPro® systems;
- developing a molecular diagnostics franchise that incorporates three distinct testing platforms, Solana®, AmpliVue®, and Savanna® and that leverages our molecular assay development competencies; and
- strengthening our position with distribution partners and our end-user customers to gain more emphasis on our products.

Our current initiatives to execute this strategy include the following:

- provide products that can compete effectively in the healthcare market where cost and quality are important;
- complete the integration of the Triage and BNP Businesses acquired in late 2017;
- strengthen and leverage our international infrastructure to support the integration of the Triage and BNP Businesses and enhance our global footprint to support our international operations and future growth;
- 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 strategy to develop differentiated technologies and products;
- strengthen our market and brand leadership in current markets by acquiring and/or developing and introducing clinically superior diagnostic solutions;
- strengthen our direct sales force to enhance relationships with integrated delivery networks, laboratories and hospitals, with a goal of driving growth through improved physician and laboratorian satisfaction;
- leverage our wireless connectivity and data management systems, including cloud-based tools;
- support payer evaluation of diagnostic tests and establishment of favorable reimbursement rates;
- provide clinicians with validated studies that encompass the clinical efficacy and economic efficiency of our diagnostic tests for the professional market;
- create strong global alliances to support our efforts to achieve leadership in key markets and expand our presence in emerging markets;
- further refine our manufacturing efficiencies and productivity improvements to increase profit; and
- focus on innovative products and markets and leverage our core competency in new product development.

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

Outlook

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

Results of Operations

Comparison of years ended December 31, 2018 and 2017

Total Revenues

The following table compares total revenues for the years ended December 31, 2018 and 2017 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2018	2017	$	%
Rapid Immunoassay	$183,160	$165,099	$18,061	11 %
Cardiac Immunoassay	266,524	47,030	219,494	467%
Specialized Diagnostic Solutions	53,243	51,978	1,265	2 %
Molecular Diagnostic Solutions	19,358	13,636	5,722	42 %
Total revenues	$522,285	$277,743	$244,542	88 %

For the year ended December 31, 2018, total revenues increased 88% to $522.3 million. The increase in total revenues was driven primarily by Cardiac Immunoassay full year impact of revenue from the acquisition of the Triage and BNP Businesses. The Company also realized increases in Rapid Immunoassay revenues due primarily to growth in influenza products, bolstered by a robust cold and flu season in the first quarter of 2018. Molecular products were up 42% over prior year driven by continued revenue growth on the Solana platform.

Gross Profit

Gross profit increased by 102% over prior year, to $315.7 million, or 60% of revenue for the year ended December 31, 2018, compared to $156.1 million, or 56% of revenue for the year ended December 31, 2017. The increased gross profit was mainly driven by the full year impact of the Cardiac Immunoassay products from the acquisition of the Triage and BNP Businesses and increased influenza sales in the current year. Gross margins increased by 420 basis points during 2018 due to higher volumes with the addition of Cardiac Immunoassay products, lower inventory step-up amortization and improved product mix in the current year.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2018 and 2017 (in thousands, except percentages):

	For the year ended December 31,								
	2018			2017					
	Operating expenses	As a % of total revenues		Operating expenses	As a % of total revenues		Increase (decrease) $	%	
Research and development	$51,649	10	%	$33,644	12	%	$18,005	54	%
Sales and marketing	$108,987	21	%	$67,248	24	%	$41,739	62	%
General and administrative	$44,951	9	%	$29,192	11	%	$15,759	54	%
Acquisition and integration costs	$14,197	3	%	$16,506	6	%	$(2,309)	(14)	%

Research and Development Expense

Research and development expense for the year ended December 31, 2018 increased from $33.6 million to $51.6 million due primarily to additional expenses associated with the Triage Business and investments in the Savanna molecular diagnostic platform.

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

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

Sales and Marketing Expense

Sales and marketing expense for the year ended December 31, 2018 increased from $67.2 million to $109.0 million primarily driven by increased expenses associated with the newly acquired Triage and BNP Businesses in October 2017. Increases were also driven by higher compensation costs associated with additional headcount and higher freight costs related to increased sales volumes during 2018.

General and Administrative Expense

General and administrative expense for the year ended December 31, 2018 increased from $29.2 million to $45.0 million primarily due to additional costs associated with the Triage and BNP Businesses, higher professional fees and higher compensation costs associated with improved company performance.

Acquisition and Integration Costs

Acquisition and integration costs for the year ended December 31, 2018 decreased from $16.5 million last year to $14.2 million this year primarily driven by lower acquisition costs and reduced integration activity. It is expected that the costs associated with the integration of the Triage and BNP Businesses will continue to decline as we advance in our integration efforts.

Other Expense, Net

Interest expense, net increased from $17.6 million to $24.3 million. Interest expense includes accretion of interest on the deferred consideration, coupon and accretion of interest related to our Convertible Senior Notes and interest and amortization of deferred financing costs associated with the Term Loan and Revolving Credit Facility. The increase in interest expense of $6.7 million over the prior year was primarily due to the accretion of interest on deferred consideration related to the BNP Business and interest incurred under the Term Loan and Revolving Credit Facility. These increases were partially offset by lower interest expense associated with the Convertible Senior Notes due to conversions into common stock during 2018.

Loss on extinguishment of debt of $8.3 million for the year ended December 31, 2018 relates to the $161.8 million early payment on the Term Loan, the extinguishment of $108.8 million in aggregate principal of the Convertible Senior Notes in exchange for the Company’s common stock during the period and the write-off of certain previously capitalized costs relating to the Term Loan due to the modification of the Credit Agreement.

Income Taxes

On December 22, 2017, the U.S. government enacted comprehensive tax legislation referred to as the Tax Cuts and Jobs Act (the “Tax Act”). Shortly after the Tax Act was enacted, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which provided guidance on accounting for the Tax Act’s impact. SAB 118 provides a measurement period, which should not extend beyond one year from the Tax Act enactment date, during which a company acting in good faith may complete the accounting for the impacts of the Tax Act under ASC Topic 740. In accordance with SAB 118, the Company must reflect the income tax effects of the Tax Act in the reporting period in which the accounting under ASC Topic 740 is complete.

During the quarter ended December 31, 2018, the Company completed its accounting for the impacts of the Tax Act. For further information, see Note 4 “Income Taxes” in the Notes to Consolidated Financial Statements in this Annual Report. We recognized an income tax benefit of $10.8 million and an expense of $0.1 million for the years ended December 31, 2018 and 2017, respectively. The primary factors contributing to the benefit in 2018 was the reversal of a significant portion of the Company’s deferred tax valuation allowance, the tax deduction from equity compensation and the generation of research credits.

The Company’s improved profitability and outlook allowed the Company to reverse the majority of its valuation allowance. During the fourth quarter of 2018, the Company performed an analysis to determine the likelihood of realizing its deferred tax assets. This analysis consisted of the evaluation of all available positive and negative

evidence, including the Company's improved profitability in 2018 (which resulted in the Company having three years of cumulative income as of December 31, 2018), combined with future projections of profitability. Because of this analysis, the Company concluded that it

was more likely than not that the majority of its U.S. deferred tax assets will be realized, and therefore reversed most of the valuation allowance. This reversal resulted in a one-time income tax benefit of $13.4 million. For further discussion, see Note 4 “Income Taxes” in the Notes to Consolidated Financial Statements in this Annual Report.

Comparison of years ended December 31, 2017 and 2016

Total Revenues

The following table compares total revenues for the years ended December 31, 2017 and 2016 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2017	2016	$	%
Rapid Immunoassay	$165,099	$121,416	$43,683	36 %
Cardiac Immunoassay	47,030	—	47,030	100 %
Specialized Diagnostic Solutions	51,978	60,681	(8,703)	(14)%
Molecular Diagnostic Solutions	13,636	9,506	4,130	43 %
Total revenues	$277,743	$191,603	$86,140	45 %

For the year ended December 31, 2017, total revenue increased 45% to $277.7 million. The increase in total revenues was primarily driven by the incremental Cardiac Immunoassay revenue from the acquisition of the Triage and BNP Businesses in October 2017 discussed further in Note 12 to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report. In addition, the Company realized increases in Rapid Immunoassay revenues due primarily to growth in influenza and Strep A products, bolstered by a severe cold and flu season. The increase in our Molecular Diagnostic Solutions was driven by gains on our Solana platform and higher sales of Strep A due to the cold and flu season. These increases were partially offset by decreased sales within our Specialized Diagnostics solutions category. This category includes Virology, Bone Health and Complement products and grants and royalty revenues. The year over year decrease was due to the satisfaction of the terms of the Bill and Melinda Gates grant in the third quarter of 2016, leaving no grant revenue recognized in 2017.

Gross Profit

Gross profit for the year ended December 31, 2017 increased by 40% as compared to the prior year, to $156.1 million, or 56% of revenue, as compared to $111.7 million, or 58% of revenue, for the year ended December 31, 2016. Gross margins declined slightly during 2017 due to the amortization of inventory step-up to fair value and intangible assets associated with the acquisition of Triage and BNP Businesses.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2017 and 2016 (in thousands, except percentages):

	For the year ended December 31,					
	2017			2016		
	Operating expenses	As a % of total revenues		Operating expenses	As a % of total revenues	
						Increase (decrease)
						$ %
Research and development	$33,644	12	%	$38,672	20 %	$(5,028) (13)%
Sales and marketing	$67,248	24	%	$50,436	26 %	$16,812 33 %
General and administrative	$29,192	11	%	$26,351	14 %	$2,841 11 %
Acquisition and integration costs	$16,506	6	%	$711	— %	$15,795 2,222 %

Research and Development Expense

Research and development expense for the year ended December 31, 2017 decreased from $38.7 million to $33.6 million primarily due to a decrease in development spending for the Savanna MDx platform and lower spend on clinical trial activities. These decreases are partially offset by additional expenses associated with the Triage and BNP Businesses.

40

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

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

Sales and Marketing Expense

Sales and marketing expense for the year ended December 31, 2017 increased from $50.4 million to $67.2 million primarily driven by expenses associated with the acquired Triage and BNP Businesses in October 2017 and the InflammaDry and AdenoPlus diagnostic business from RPS Diagnostics in May 2017.

General and Administrative Expense

General and administrative expense for the year ended December 31, 2017 increased from $26.4 million to $29.2 million primarily due to higher incentive compensation and additional costs associated with the Triage and BNP Businesses. General and administrative expense primarily includes personnel costs, information technology, facilities and professional service fees.

Acquisition and Integration Costs

Acquisition and integration costs for the year ended December 31, 2017 increased to $16.5 million from $0.7 million in 2016 primarily attributable to due diligence and integration costs related to the acquisition of the Triage and BNP Businesses on October 6, 2017.

Other Expense, Net

Interest expense, net primarily relates to accrued interest for the coupon and accretion of the discount on our $172.5 million 3.25% Convertible Senior Notes issued in December 2014, accrued interest and amortization of deferred loan costs associated with the Senior Credit Facility, and interest paid on our lease obligation associated with our San Diego McKellar facility. The increase in interest expense of $5.4 million for the year ended December 31, 2017 was primarily due to the interest incurred under the Senior Credit Facility entered into in connection with the acquisition of the Triage and BNP Businesses. Gain on extinguishment of debt for the year ended December 31, 2016 related to the purchase of $5.2 million in aggregate principal of our Convertible Senior Notes.

Income Taxes

We recognized an income tax expense of $0.1 million and a benefit of $2.4 million for the years ended December 31, 2017 and 2016, respectively. The primary factors contributing to our tax expense in 2017 is the recognition of $0.4 million of deferred tax expenses from indefinite-lived assets, namely goodwill that is being amortized for tax, and current tax expense of $0.3 million related to state income taxes. These expenses were offset by an income tax benefit of $0.6 million for alternative minimum tax (AMT) credits which are now refundable based on the law changes in the Tax Act.

Liquidity and Capital Resources

As of December 31, 2018 and 2017, our principal sources of liquidity consisted of the following (in thousands):

	December 31,	
	2018	2017
Cash, cash equivalents, and restricted cash	$43,695	$36,086
Amount available to borrow under the Revolving Credit Facility	$121,812	$15,000
Working capital including cash, cash equivalents, and restricted cash	$33,662	$202,881
Adjusted working capital (1)	$88,041	$202,881

(1) Adjusted working capital as of December 31, 2018 excludes the current portion of the Convertible Senior Notes of $54.4 million as such notes may be settled at the Company’s option in cash or a combination of cash and shares of common stock.

41

As of December 31, 2018, we had $43.7 million in cash and cash equivalents, a $7.6 million increase from the prior year. 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 and integration activities, competition and technological developments and the time and expenditures required to obtain governmental approval of our products. In addition, we intend to continue to evaluate candidates for new product lines, company or technology acquisitions or technology licensing. If we decide to proceed with any such transactions, we may need to incur additional debt or issue additional equity, to successfully complete the transactions.

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

- support of commercialization efforts related to our current and future products, including support of our direct sales force and field support resources;
- interest on and repayments of our Convertible Senior Notes, Revolving Credit Facility, deferred consideration, contingent consideration and lease obligations;
- the continued advancement of research and development efforts;
- acquisitions of equipment and other fixed assets for use in our current and future manufacturing and research and development facilities;
- the integration of our recent acquisitions; and
- potential strategic acquisitions and investments.

The Amended and Restated Credit Agreement provides us with a Revolving Credit Facility of $175.0 million, of which $53.2 million was outstanding as of December 31, 2018. The Revolving Credit Facility matures on August 31, 2023.

Our Convertible Senior Notes due in 2020 have a coupon rate of 3.25% and are convertible as of December 31, 2018. The principal balance outstanding as of December 31, 2018 was $58.5 million. During the year ended December 31, 2018, $108.8 million in principal was settled for 3.7 million shares of our common stock. See Note 3 of the Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report under the heading “Convertible Senior Notes”.

As of December 31, 2018, we have $19.1 million in fair value of contingent considerations and $187.2 million of deferred consideration associated with acquisitions to be settled in future periods.

On December 12, 2018, the Company’s Board of Directors authorized a new stock repurchase program, pursuant to which up to $50.0 million of the Company’s shares of common stock may be purchased through December 12, 2020.

We expect our revenue and operating expenses will significantly impact our cash management decisions. Our future capital requirements and the adequacy of our available funds to service our long-term debt and to fund working capital expenditures and business development efforts will depend on many factors, including:

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

Cash Flow Summary

	Year ended December 31,		
	2018	2017	2016
Net cash provided by operating activities	$136,345	$27,709	$11,815
Net cash provided by (used for) investing activities	114,955	(431,759)	(16,970)
Net cash (used for) provided by financing activities	(244,058)	270,608	(16,799)
Effect of exchange rate changes on cash	367	20	(9)
Net increase (decrease) in cash and cash equivalents	$7,609	$(133,422)	$(21,963)

Cash provided by operating activities of $136.3 million during the year ended December 31, 2018 reflects net income of $74.2 million and non-cash charges of $64.5 million, primarily related to depreciation, amortization of intangible assets, changes in deferred tax assets and liabilities, stock-based compensation, accretion of interest on deferred consideration related to the acquired BNP Business, and loss on extinguishment of debt related to Term Loan and Convertible Senior Notes. Partially offsetting these cash inflows was a net working capital use of cash of $7.1 million.

Cash provided by operating activities of $27.7 million during the year ended December 31, 2017 reflects net loss of $8.2 million for the year ended December 31, 2017 and non-cash charges of $59.7 million primarily related to depreciation, amortization of intangible assets, amortization of the inventory step-up to fair value related to the Triage and BNP Businesses acquired in 2017, stock-based compensation, amortization of debt discount and deferred issuance costs and accretion of interest on deferred consideration related to the acquired BNP Business. Partially offsetting these cash inflows was a net working capital use of cash of $30.7 million.

Cash provided by operating activities of $11.8 million during the year ended December 31, 2016 reflects net loss of $13.8 million for the year ended December 31, 2016 and non-cash charges of $33.2 million primarily related to depreciation, amortization and stock-based compensation. Partially offsetting these cash inflows was net working capital use of cash of $1.9 million.

Our investing activities provided $115.0 million during the year ended December 31, 2018 primarily from the sale of the Summers Ridge property for $146.6 million. In addition, we used $31.7 million to acquire production equipment, building improvements and Sofia, Solana and Triage instruments available for sale or lease. Our investing activities used $431.8 million during the year ended December 31, 2017 primarily for the acquisition of the Triage and BNP Businesses. Additionally, we used $13.7 million for the acquisition of the InflammaDry and AdenoPlus diagnostic business from RPS Diagnostics and $17.5 million primarily for the acquisition of production equipment, Sofia and Solana instruments available for sale or lease and building improvements. Our investing activities used $17.0 million during the year ended December 31, 2016; $5.1 million for the acquisition of Immutopics, and $11.9 million primarily for the acquisition of production equipment, Sofia and Solana instruments available for sale or lease, and building improvements.

We are currently planning approximately $39.0 million in capital expenditures over the next 12 months. The primary purpose for our capital expenditures is to acquire manufacturing and scientific equipment, to implement facility improvements, to acquire instruments to be leased to customers and to purchase or develop information technology. We plan to fund these capital expenditures with the cash on our balance sheet. We have $9.1 million in firm purchase commitments with respect to planned inventory purchases as of December 31, 2018.

Cash used by financing activities was $244.1 million during the year ended December 31, 2018 primarily related to payments on the Term Loan of $161.8 million, payments on the Revolving Credit Facility of $40.0 million, payments on deferred consideration of $46.0 million, repurchases of common stock of $4.3 million, payments of $2.0 million of transaction costs related to the exchange of Convertible Senior Notes for common stock and payments of acquisition contingent consideration of $6.3 million, partially offset by proceeds from issuance of stock of $17.0 million from stock option exercises. Cash provided by financing activities was $270.6 million during the year ended December 31, 2017 and was primarily related to proceeds from the issuance of the Term Loan and initial advances under the Revolving Credit Facility. Additional cash was provided by the issuance of common stock of $25.4 million upon the exercise of stock options, partially offset by payment on debt issuance costs of $8.7 million. Cash used by financing activities was $16.8 million during the year ended December 31, 2016, of which $20.2 million was used for repurchases of common stock primarily related to our share repurchase program, and $4.5 million was used for the

repurchase of some of the Convertible Senior Notes. These amounts were partially offset by proceeds from the issuance of common stock of $8.6 million upon the exercise of stock options.

Off-Balance Sheet Arrangements

At December 31, 2018 and 2017, 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, 2018, 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)	$62,305	$ 1,901	$60,404	$—	$ —
Revolving Credit Facility (2)	66,493	2,873	8,363	55,257	—
Deferred consideration (3)	210,000	44,000	84,000	82,000	—
Lease obligation (4)	1,923	956	967	—	—
Operating lease obligations (5)	135,214	9,940	21,103	17,374	86,797
Non-cancelable purchase commitment (6)	9,057	6,688	1,116	279	974
Total contractual obligations	$484,992	$ 66,358	$175,953	$154,910	$ 87,771

(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) Includes the principal amount of our Revolving Credit Facility due in August 2023, as well as interest payments and commitment fees to be made quarterly.

(3) Reflects the deferred consideration payments related to the acquisition of the BNP Business.

(4) Reflects our lease obligation on the approximately 78,000 square-foot McKellar San Diego facility in place as of December 31, 2018. The facility is subject to a financing arrangement with payments through December 2020. Our future obligation under this financing arrangement is included in the table above.

(5) Reflects future minimum lease obligations on facilities and equipment under operating leases in place as of December 31, 2018. On January 5, 2018, we entered into a lease for two of the four buildings on the Summers Ridge facility. Such lease is subject to certain must-take provisions related to two additional buildings. Operating lease obligations excludes one building for which the must-take clause has not been triggered.

(6) Reflects our $9.1 million of non-cancelable commitments for planned inventory purchases under contractual arrangements.

We have entered into various licensing agreements, which largely require payments based on specified product sales as well as the achievement of specific milestones. Royalty and license expenses under these various royalty and licensing agreements collectively totaled $0.4 million, $0.6 million and $0.8 million for the years ended December 31, 2018, 2017 and 2016, 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, 2018, we had approximately $3.2 million of liabilities associated with uncertain tax positions. See Note 4 in the Consolidated Financial Statements included in this Annual Report for further discussion of uncertain tax positions. The table also excludes $19.1 million in potential contingent consideration payments primarily related to the acquisition of the BNP Business and achievement of certain revenue targets under other acquisition agreements. We have not included amounts in the table because we cannot make a reasonably reliable estimate regarding the probability of the annual payments for the BNP Business or whether and when the milestones required for the other acquisition payments will be

achieved. See Note 10 in the Consolidated Financial Statements included in this Annual Report for further discussion of our contingent consideration.

Recent Accounting Standards

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

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, stock-based compensation, goodwill and intangibles, business combinations, income taxes and convertible debt. 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:

Reserve for Contractual Rebates and Discounts

The Company records revenues primarily from product sales. These revenues are recorded net of rebates and other discounts that are estimated at the time of sale, and are largely driven by various customer program offerings, including special pricing agreements, promotions and other volume-based incentives. Rebates and discounts are recorded as a reduction of sales and trade accounts receivable, based up on historical experience, estimated discounting levels and estimated distributor inventory balances.

Stock-Based Compensation

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

Compensation expense for time-based restricted stock units are measured at the grant date and recognized ratably over the vesting period. We determine the fair value of time-based and performance-based restricted stock units based on the closing market price of our common stock on the grant date. The recognition of compensation expense associated with performance-based restricted stock units 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.

For purposes of measuring compensation expense, the number of shares ultimately expected to vest is estimated at each reporting date based on management’s expectations regarding the relevant performance criteria. The grant date of the performance-based restricted stock units 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 units.

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, which has an indefinite life, is not amortized but instead is 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, 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. If the fair value of a reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, goodwill is 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. We completed our annual evaluation for impairment of goodwill as of December 31, 2018 and determined that no impairment existed.

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 an 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 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.

Income Taxes

Significant judgment is required in determining our provision for income taxes, current tax assets and liabilities, deferred tax assets and liabilities, and our future taxable income, both as a whole and in various tax jurisdictions, for purposes of assessing our ability to realize future benefit from our deferred tax assets. A valuation allowance may be established to reduce our deferred tax assets to the amount that is considered more likely than not to be realized through the generation of future taxable income and other tax planning opportunities. In 2016 and 2017, we evaluated our gross deferred tax assets, including an assessment of cumulative income or loss over the prior three-year period and future periods, to determine if a valuation allowance was required. A significant piece of objective negative evidence evaluated was the cumulative before-tax loss incurred over the three-year periods ended December 31, 2017 and 2016. Such objective evidence limits the ability to consider other subjective evidence such as our projections for future profitability. In 2018, the Company re-evaluated the positive and negative evidence surrounding its valuation allowance position. On the basis of this evaluation, as of December 31, 2018, we reversed $13.4 million of our valuation allowance. There is a valuation allowance of $1.8 million recorded that presents the portion of the deferred tax assets that management believes is not more likely than not to be realized. We will continue to assess the need for

a valuation allowance on our deferred tax assets by evaluating both positive and negative evidence that may exist. We recognize liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained during an audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While we

believe that we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcome of examinations by tax authorities in determining the adequacy of our provision for income taxes. See Note 4 in the Consolidated Financial Statements included in this Annual Report for more information on income taxes.

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 3 in the Consolidated Financial Statements included in this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

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

The fair market value of our Revolving Credit Facility interest rate debt is subject to interest rate risk. Generally, the fair market value of the Revolving Credit Facility interest rate debt will vary as interest rates increase or decrease. We had $53.2 million outstanding under our Revolving Credit Facility with an interest rate of 4.71% as of December 31, 2018. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would increase our annual interest expense by approximately $0.5 million. Based on our market risk sensitive instruments outstanding at December 31, 2018, we have determined that there was no material market risk exposure from such instruments to our consolidated financial position, results of operations or cash flows as of such dates.

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, 2018, our cash and cash equivalents were placed in the Company's highly liquid operating accounts.

Foreign Currency Exchange Risk

We are exposed to foreign currency risks that arise from normal business operations. These risks include the translation of local currency balances of foreign subsidiaries, transaction gains and losses associated with intercompany loans with foreign subsidiaries and transactions denominated in currencies other than a location's functional currency. Through December 31, 2018, we did not hedge against exchange rate fluctuations, which means that we were fully exposed to exchange rate changes. In addition, we have certain agreements whereby we share the foreign currency exchange fluctuation risk.

During the year ended December 31, 2018, we generated approximately $142.3 million in revenue denominated in currencies other than the U.S. dollar. The major currencies to which our revenues are exposed are the Euro and the Chinese Yuan. A 100 basis point move in the average exchange rates (assuming a simultaneous and immediate 100 basis point change for the relevant period) would have resulted in an increase or decrease in our reported revenue for the year ended December 31, 2018 as follows (in thousands):

Currency

	Year ended December 31, 2018
Chinese Renminbi	$ 580
Euro	$ 490

Effective fiscal year 2019, the Company has initiated a foreign currency management policy which permits the use of derivative instruments, such as forward contracts, to reduce volatility in our results of operations resulting from foreign

exchange rate fluctuations. We do not enter into foreign currency derivative instruments for trading purposes or to engage in speculative activity.

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

Report of Independent Registered Public Accounting Firm	50
Consolidated Balance Sheets as of December 31, 2018 and 2017	51
Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016	52
Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2018, 2017 and 2016	53
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018, 2017 and 2016	54
Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016	55
Notes to Consolidated Financial Statements	57
Schedule II Consolidated Valuation and Qualifying Accounts	78

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Quidel Corporation
Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of Quidel Corporation (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2018 and the related notes and schedule listed in the Index at Item 15(a)(2) (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with US generally accepted accounting principles.
We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 15, 2019 expressed an unqualified opinion thereon.
Basis for Opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.
/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.

San Diego, California
February 15, 2019

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

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$43,695	$36,086
Accounts receivable, net	58,677	67,046
Inventories	67,379	67,078
Assets held for sale	—	146,644
Prepaid expenses and other current assets	23,646	14,375
Total current assets	193,397	331,229
Property, plant and equipment, net	73,901	61,585
Goodwill	337,021	337,028
Intangible assets, net	175,029	203,827
Deferred tax asset—non-current	22,192	—
Other non-current assets	4,831	1,582
Total assets	$806,371	$935,251
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$25,171	$27,279
Accrued payroll and related expenses	19,210	15,926
Current portion of contingent consideration	3,983	6,293
Current portion of deferred consideration	44,000	46,000
Current portion of Revolving Credit Facility	—	10,000
Current portion of Convertible Senior Notes	54,379	—
Current portion of Term Loan	—	10,184
Other current liabilities	12,992	12,666
Total current liabilities	159,735	128,348
Convertible Senior Notes	—	149,868
Term Loan	—	227,394
Revolving Credit Facility	53,188	—
Deferred consideration - non-current	143,158	177,158
Contingent consideration - non-current	15,129	18,008
Deferred tax liability - non-current	—	430
Other non-current liabilities	9,577	6,941
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $.001 par value per share; 5,000 shares authorized; none issued or outstanding at December 31, 2018 and 2017	—	—
Common stock, $.001 par value per share; 97,500 shares authorized; 39,386 and 34,540 shares issued and outstanding at December 31, 2018 and 2017, respectively	39	35
Additional paid-in capital	363,921	239,489
Accumulated other comprehensive loss	(139)	—
Retained earnings (accumulated deficit)	61,763	(12,420)
Total stockholders' equity	425,584	227,104
Total liabilities and stockholders' equity	$806,371	$935,251

See accompanying notes.

51

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

	Year ended December 31,		
	2018	2017	2016
Total revenues	$522,285	$277,743	$191,603
Cost of sales	206,572	121,601	79,872
Gross profit	315,713	156,142	111,731
Research and development	51,649	33,644	38,672
Sales and marketing	108,987	67,248	50,436
General and administrative	44,951	29,192	26,351
Acquisition and integration costs	14,197	16,506	711
Total operating expenses	219,784	146,590	116,170
Operating income (loss)	95,929	9,552	(4,439)
Other expense, net			
Interest expense, net	(24,283)	(17,588)	(12,181)
(Loss) gain on extinguishment of debt	(8,262)	—	421
Total other expense, net	(32,545)	(17,588)	(11,760)
Income (loss) before income taxes	63,384	(8,036)	(16,199)
(Benefit) provision for income taxes	(10,799)	129	(2,391)
Net income (loss)	$74,183	$(8,165)	$(13,808)
Basic earnings (loss) per share	$1.95	$(0.24)	$(0.42)
Diluted earnings (loss) per share	$1.86	$(0.24)	$(0.42)
Shares used in basic per share calculation	37,995	33,734	32,708
Shares used in diluted per share calculation	42,554	33,734	32,708

See accompanying notes.

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

	Year ended December 31,		
	2018	2017	2016
Net income (loss)	$74,183	$(8,165)	$(13,808)
Other comprehensive (loss) income, net of tax			
Changes in cumulative translation adjustment	(139)	53	(22)
Comprehensive income (loss)	$74,044	$(8,112)	$(13,830)

See accompanying notes.

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

	Common Stock					
	Shares	Par	Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings (accumulated deficit)	Total stockholders' equity
Balance at January 1, 2016	33,323	$33	$209,121	$ (31)	$ 9,553	$218,676
Issuance of common stock under equity compensation plans	755	—	9,365	—	—	9,365
Stock-based compensation expense	—	—	7,134	—	—	7,134
Repurchase of Convertible Senior Notes	—	—	(547)	—	—	(547)
Repurchases of common stock	(1,181)	—	(20,168)	—	—	(20,168)
Changes in cumulative translation adjustment, net of tax	—	—	—	(22)	—	(22)
Net loss	—	—	—	—	(13,808)	(13,808)
Balance at December 31, 2016	32,897	33	204,905	(53)	(4,255)	200,630
Issuance of common stock under equity compensation plans	1,669	2	26,077	—	—	26,079
Stock-based compensation expense	—	—	9,048	—	—	9,048
Repurchases of common stock	(26)	—	(541)	—	—	(541)
Changes in cumulative translation adjustment, net of tax	—	—	—	53	—	53
Net loss	—	—	—	—	(8,165)	(8,165)
Balance at December 31, 2017	34,540	35	239,489	—	(12,420)	227,104
Issuance of common stock under equity compensation plans	1,237	—	17,047	—	—	17,047
Stock-based compensation expense	—	—	10,078	—	—	10,078
Issuance of shares in exchange for Convertible Senior Notes	3,699	4	200,215	—	—	200,219
Tax impact from the conversion of Convertible Senior Notes	—	—	2,162	—	—	2,162
Reduction for equity component of Convertible Senior Notes exchanged	—	—	(100,726)	—	—	(100,726)
Repurchases of common stock	(90)	—	(4,344)	—	—	(4,344)
Changes in cumulative translation adjustment, net of tax	—	—	—	(139)	—	(139)
Net income	—	—	—	—	74,183	74,183
Balance at December 31, 2018	39,386	$39	$363,921	$ (139)	$ 61,763	$425,584

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENT OF CASH FLOWS
(in thousands)

	Year ended December 31,		
	2018	2017	2016
OPERATING ACTIVITIES			
Net income (loss)	$74,183	$(8,165)	$(13,808)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation, amortization and other	46,266	30,762	22,796
Stock-based compensation expense	11,709	9,061	7,986
Amortization of debt discount and deferred issuance costs	3,952	6,022	5,891
Change in fair value of acquisition contingencies	1,114	(81)	(485)
Accretion of interest on deferred consideration	10,000	2,608	—
Amortization of inventory step-up to fair value	3,650	10,950	—
Change in deferred tax assets and liabilities	(20,458)	365	(2,603)
Loss (gain) on extinguishment of debt	8,262	—	(421)
Changes in assets and liabilities:			
Accounts receivable	8,236	(42,052)	(6,265)
Inventories	(3,974)	362	859
Prepaid expenses and other current and non-current assets	(12,681)	(9,113)	(489)
Accounts payable	(331)	12,956	4,323
Accrued payroll and related expenses	1,674	7,130	(375)
Other current and non-current liabilities	4,743	6,904	(5,594)
Net cash provided by operating activities	136,345	27,709	11,815
INVESTING ACTIVITIES			
Acquisitions of property, equipment and intangibles	(31,689)	(17,510)	(11,909)
Acquisition of other businesses, net of cash acquired	—	(14,451)	(5,061)
Acquisition of Triage and BNP Businesses	—	(399,798)	—
Proceeds from sale of Summers Ridge Property	146,644	—	—
Net cash provided by (used for) investing activities	114,955	(431,759)	(16,970)
FINANCING ACTIVITIES			
Proceeds from issuance of Term Loan	—	245,000	—
Proceeds from issuance of Revolving Credit Facility	—	10,000	—
Proceeds from issuance of common stock	17,047	25,426	8,575
Payments of debt issuance costs	(513)	(8,682)	—
Payments on lease obligation	(130)	(98)	(540)
Payments on Revolving Credit Facility	(40,000)	—	—
Repurchases of common stock	(4,344)	(541)	(20,168)
Repurchases of Convertible Senior Notes	—	—	(4,459)
Payments on acquisition contingent consideration	(6,303)	(497)	(207)
Payments of deferred consideration	(46,000)	—	—
Payments of Term Loan	(161,813)	—	—
Transaction costs related to debt exchange	(2,002)	—	—
Net cash (used for) provided by financing activities	(244,058)	270,608	(16,799)
Effect of exchange rate changes on cash	367	20	(9)
Net increase (decrease) in cash and cash equivalents	7,609	(133,422)	(21,963)
Cash and cash equivalents, beginning of period	36,086	169,508	191,471
Cash and cash equivalents, at end of period	$43,695	$36,086	$169,508

55

	Year ended December 31,		
	2018	2017	2016
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid during the period for interest	$7,929	$9,137	$6,488
Cash paid during the period for income taxes	$6,923	$1,274	$490
NON-CASH INVESTING ACTIVITIES			
Purchase of property, equipment and intangibles by incurring current liabilities	$1,785	$1,446	$3,280
NON-CASH FINANCING ACTIVITIES			
Decrease of accrued payroll and related expenses upon issuance of common stock	$—	$903	$539
Receivable for stock option exercises	$—	$—	$251
Deferred consideration for acquisition of BNP Business	$—	$220,550	$—
Extinguishment of Convertible Senior Notes through issuance of stock	$200,219	$—	$—
Principal amount of Term Loan exchanged for Revolving Credit Facility	$83,187	$—	$—

See accompanying notes.

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Note 1. Company Operations and Summary of Significant Accounting Policies
Quidel Corporation (the "Company") commenced operations in 1979. The Company operates in one business segment, which develops, manufactures and markets rapid diagnostic testing solutions. These diagnostic tests can be categorized in the following product categories: Rapid Immunoassay, Cardiac Immunoassay, Specialized Diagnostic Solutions and Molecular Diagnostic Solutions. 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 through a network of distributors and a direct sales force and temporary transition service arrangements entered into with Abbott Laboratories in connection with the acquisition of the Triage and BNP Businesses.
The accompanying consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with generally accepted accounting principles in the U.S.
Consolidation—The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.
Cash and Cash Equivalents—The Company considers cash equivalents to be highly liquid investments with a maturity at the date of purchase of three months or less. The Company invests its cash equivalents primarily in money market funds with high quality institutions.
Accounts Receivable—The Company sells its products directly to hospitals and reference laboratories as well as to distributors in the U.S. and sells directly to hospitals and labs and through distribution internationally (see Note 9). 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 $12.0 million and $12.3 million at December 31, 2018 and 2017, respectively.
Concentration of Credit Risk—Financial instruments that potentially subject the Company to significant concentrations of credit risk consists principally of trade accounts receivable.
The Company performs credit evaluations of its customers' financial condition and limits the amount of credit extended when deemed necessary, but generally requires no collateral. Credit quality is monitored regularly by reviewing credit history. The Company believes that the concentration of credit risk in its trade accounts receivables is moderated by its credit evaluation process, relatively short collection terms, the high level of credit worthiness of its customers, and letters of credit issued on the Company's behalf. Potential credit losses are limited to the gross value of accounts receivable.
Inventories—Inventories are stated at the lower of cost (first-in, first-out) or net realizable value. The Company reviews the components of its inventory on a quarterly basis for excess, obsolete and impaired inventory and makes appropriate dispositions as obsolete stock is identified.
Assets Held for Sale—Assets to be disposed that meet the held for sale criteria are reported at the lower of their carrying amount and fair value, less costs to sell, and are no longer depreciated.
Property, Plant and Equipment—Property, plant and equipment is recorded at cost and depreciated over the estimated useful lives of the assets (three to fifteen years) using the straight-line method. Amortization of leasehold improvements is computed on the straight-line method over the estimated useful lives of the assets.

Goodwill and Intangible Assets—Intangible assets are recorded at cost and amortized on a straight-line basis over their estimated useful lives, except for indefinite-lived intangibles such as goodwill. Software development costs associated with software to be 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.

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 3 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. These rebates and discounts 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 is recognized when control of the products is transferred to the customers in an amount that reflects the consideration the Company expects to receive from the customers in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract and the contract price, allocating the contract price to the distinct performance obligations in the contract and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. A performance obligation is considered to be satisfied once the control of a product is transferred to the customer or the service is provided to the customer, meaning the customer has the ability to use and obtain the benefit of the goods or service. The Company recognizes revenue for satisfied performance obligations only when there are no uncertainties regarding payment terms or transfer of control.

A portion of product sales includes revenues for diagnostic kits, which are utilized on leased instrument systems under the Company's "reagent rental" program. The reagent rental program provides customers the right to use the instruments at no separate cost to the customer in consideration for a multi-year agreement to purchase annual minimum amounts of consumables ("reagents" or "diagnostic kits"). When an instrument is placed with a customer under a reagent rental agreement, the Company retains title to the equipment and it remains capitalized on the Company's Consolidated Balance Sheets as property, plant and equipment, net. The instrument is depreciated on a straight-line basis over the lesser of the lease term or life of the instrument. Depreciation expense is recorded in cost of sales included in the Consolidated Statements of Operations. Instrument and consumables under the reagent rental agreements are deemed two distinct performance obligations. Though the instrument and consumables do not have any use to customers without one another, they are not highly interdependent because they do not significantly affect each other. The Company would be able to fulfill its promise to transfer the instrument even if its customers did not purchase any consumables and the Company would be able to fulfill its promise to provide the consumables even if customers acquired instruments separately. The contract price is allocated between these two performance obligations based on the relative standalone selling prices. The instrument is considered an operating lease and revenue allocated to the instrument will be separately disclosed, if material.

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.

From time to time, the Company earns income from grants for research and commercialization activities. For the year ended December 31, 2016, the Company recognized $6.5 million as grant revenue related to 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. Cash payments received were restricted as to use until expenditures contemplated in the grant were incurred or committed. As of December 31, 2016, all payment related milestones have been achieved and all of the grant revenue was fully recognized. As such, the Company recognized no grant revenue during each of the twelve months ended December 31, 2017 and 2018.

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

Product Shipment Costs—Product shipment costs are included in sales and marketing expense in the accompanying Consolidated Statements of Operations. Shipping and handling costs were $8.3 million, $3.7 million and $3.8 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Advertising Costs—Advertising costs are expensed as incurred. Advertising costs were $0.9 million, $0.5 million and $0.3 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Deferred Rent—The Company enters into lease arrangements for office space under non-cancelable operating leases. Certain of the operating lease agreements contain rent escalation provisions, which are considered in determining the straight-line rent expense to be recorded over the lease term. The lease term begins on the date of initial possession of the leased property for purposes of recognizing lease expense on a straight-line basis over the term of the lease. The Company does not assume renewals in the determination of the lease term unless the renewals are deemed to be reasonably assured at lease inception. The difference between rent expense and amounts paid under the Company's lease agreements 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 the income tax provision.

Fair Value of Financial Instruments— The Company uses the fair value hierarchy established in Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurements and Disclosures, which requires that the valuation of assets and liabilities subject to fair value measurements 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; and

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 and cash equivalents, accounts receivables, accounts payable and accrued liabilities approximate their fair values due to their short-term nature.

Product Warranty—The Company generally sells products with a limited product warranty and certain limited indemnifications. Due to product testing, the short time between product shipment and the detection and correction of product failures and a low historical rate of payments on 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. For stock options with graded vesting, the Company ensures that the cumulative amount of compensation expense recognized at the end of any reporting period at least equals the portion of the stock option that has vested at that date. The total number of stock options expected to vest is adjusted by estimated forfeiture rates. The Company determined the estimated fair value of each stock option on the date of grant using the Black-Scholes option valuation model. The fair value of restricted stock units is determined based on the closing market price of the Company's common stock on the grant date. Compensation expense for time-based restricted stock units is measured at the grant date and recognized ratably over the vesting period. For purposes of measuring compensation expense for performance-based restricted stock units, the number of shares ultimately expected to vest is estimated at each reporting date based on management's expectations regarding the relevant performance criteria. The grant date of the PSUs takes place when the grant is authorized and the specific achievement goals are communicated.

59

Comprehensive Income (loss)—Comprehensive income (loss) includes unrealized gains and losses which are related to the cumulative translation adjustments excluded from the Company's Consolidated Statements of Operations.

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

Accounting Periods—Each of the Company's fiscal quarters end on the Sunday closest to the end of the calendar quarter. The Company's fiscal year ends are December 30, 2018, December 31, 2017 and January 1, 2017. For ease of reference, the calendar quarter end dates are used herein.

Recent Accounting Pronouncements—In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance codified in Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers, which amends the guidance in former ASC 605, Revenue Recognition ("ASU 2014-09"). 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 are required to use more judgment and make more estimates than under prior authoritative guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The FASB has issued several amendments to the new standard, which include clarification of accounting guidance related to identification of performance obligations, intellectual property licenses and principal vs. agent considerations. ASU 2014-09 and all subsequent amendments (collectively, "ASC 606") were effective for public entities for annual reporting periods beginning after December 15, 2017, including interim periods therein.

The Company adopted ASC 606 on January 1, 2018, using the modified retrospective transition method applied to those contracts which were not completed as of that date. The cumulative effect of applying the new revenue standard to all incomplete contracts as of January 1, 2018 was not material and, therefore, did not result in an adjustment to opening retained earnings. The adoption of ASC 606 did not have a material impact on the Company's consolidated financial position, results of operations, equity or cash flows as of the adoption date or for the year ended December 31, 2018.

In February 2016, the FASB issued guidance codified in ASU 2016-02 (Topic 842), Leases. The guidance requires a lessee to recognize a lease liability for the obligation to make lease payments and a right-of-use asset representing the right to use the underlying asset for the lease term on the balance sheet. Under ASU 2016-02, adoption was required on a modified retrospective transition basis for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. In July 2018, the FASB issued ASU 2018-11, which allows for an alternative method to adopt the lease standard by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption, with no adjustment to prior comparative periods. ASU 2016-02 and all subsequent amendments (collectively, "ASC 842") are effective for public entities for annual reporting periods beginning after December 15, 2018, including interim periods therein.

The Company will adopt ASC 842 on January 1, 2019 using the alternative method of adoption. We estimate that the impact of the adoption will be to add approximately $87.0 million in operating right-of-use assets; increase the current portion of operating lease liabilities and non-current operating lease liabilities by approximately $5.0 million and $85.0 million, respectively; and decrease current and non-current deferred rent by approximately $0.5 million and $2.5 million, respectively. There are no adjustments to retained earnings. In applying ASC 842, the Company will adopt the package of practical expedients which, among other things, allows the Company to carry forward its historical lease classification. Additionally, the Company will adopt a policy to exclude short-term leases from the calculation of the right-of-use assets and lease liabilities.

In January 2017, the FASB issued guidance codified in ASU 2017-04, Intangibles-Goodwill and Other (Topic 350) Simplifying the Test for Goodwill Impairment ("ASU 2017-04"). Under this new guidance, an entity will no longer determine goodwill impairment by calculating the implied fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. Instead, an entity will compare the fair value of a reporting unit with its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. The guidance is effective

for fiscal years beginning after December 15, 2019 including interim periods therein. The Company is currently evaluating the impact of this guidance and expects to adopt the standard in the first quarter of 2020.

Note 2. Balance Sheet Account Details

Prepaid expenses and other current assets

The following is a summary of prepaid expenses and other current assets (in thousands):

	December 31,	
	2018	2017
Receivables under transition service agreements	$15,507	$7,509
Income taxes receivable	2,703	3,806
Prepaid expenses	4,508	2,898
Other	928	162
Total prepaid expenses and other current assets	$23,646	$14,375

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or net realizable value. The following is a summary of inventories (in thousands):

	December 31,	
	2018	2017
Raw materials	$24,292	$22,252
Work-in-process (materials, labor and overhead)	21,280	22,813
Finished goods (materials, labor and overhead)	21,807	22,013
Total inventories	$67,379	$67,078

Property, Plant and Equipment

The following is a summary of property, plant and equipment (in thousands):

	December 31,	
	2018	2017
Equipment, furniture and fixtures	$89,285	$75,728
Building and improvements	37,335	34,994
Leased instruments	42,647	32,458
Land	1,080	1,080
Total property, plant and equipment, gross	170,347	144,260
Less: accumulated depreciation and amortization	(96,446)	(82,675)
Total property, plant and equipment, net	$73,901	$61,585

The equipment, furniture and fixtures category above includes construction in progress and instruments that have not been placed at a customer under a lease agreement. These items will be reclassified when the assets are placed in service. The total expense for depreciation of fixed assets and amortization of leasehold improvements was $17.7 million, $14.6 million and $13.4 million for the years ended December 31, 2018, 2017 and 2016, respectively. Maintenance and minor repairs are charged to operations as incurred.

Goodwill and Intangible Assets

The Company had goodwill of $337.0 million as of December 31, 2018, which remains consistent with December 31, 2017. Amortizable intangible assets consisted of the following (dollar amounts in thousands):

		December 31, 2018			December 31, 2017		
Description	Weighted-average useful life (years)	Gross assets	Accumulated amortization	Net	Gross assets	Accumulated amortization	Net
Purchased technology	9.1	$112,100	$(57,495)	$54,605	$112,100	$(49,614)	$62,486
Customer relationships	7.0	122,389	(27,561)	94,828	122,404	(10,960)	111,444
License agreements	9.9	6,511	(4,530)	1,981	6,515	(3,980)	2,535
Patent and trademark costs	10.8	28,740	(7,624)	21,116	28,740	(4,917)	23,823
Software development costs	5.0	6,629	(4,130)	2,499	6,630	(3,091)	3,539
Total amortizable intangible assets		$276,369	$(101,340)	$175,029	$276,389	$(72,562)	$203,827

Amortization expense related to the capitalized software costs was $1.0 million, $0.8 million and $0.5 million for the years ended December 31, 2018, 2017 and 2016, respectively. Amortization expense (including capitalized software costs) was $28.8 million, $16.1 million and $9.5 million for the years ended December 31, 2018, 2017 and 2016, respectively.

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
2019	$ 27,542
2020	27,144
2021	26,999
2022	26,468
2023	25,758
Thereafter	41,118
Total	$ 175,029

Other current liabilities

The following is a summary of other current liabilities (in thousands):

	December 31,	
	2018	2017
Customer incentives	$7,516	$7,165
Accrued interest	347	442
Other	5,129	5,059
Total other current liabilities	$12,992	$12,666

Note 3. Debt

Convertible Senior Notes

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

Deferred issuance costs related to the Convertible Senior Notes were $0.5 million and $2.1 million as of December 31, 2018 and 2017, respectively.

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

In general, for each $1,000 in principal, the "principal portion" of cash upon settlement is defined as the lesser of $1,000, or 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 effective interest rate during fiscal year 2018 was 6.6%. The Convertible Senior Notes mature on December 15, 2020. During the year ended December 31, 2018, the Company recorded total interest expense of $6.1 million related to the Convertible Senior Notes of which $3.1 million related to the amortization of the debt discount and issuance costs and $3.0 million related to the coupon due semi-annually. During the year ended December 31, 2017, the Company recorded total interest expense of $10.9 million related to the Convertible Senior Notes of which $5.5 million related to the amortization of the debt discount and issuance costs and $5.4 million related to the coupon due semi-annually. During the year ended December 31, 2016, the Company recorded total interest expense of $10.9 million related to the Convertible Senior Notes of which $5.4 million related to the amortization of the debt discount and issuance costs and $5.5 million related to the coupon due semi-annually.

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

The Company accounts separately for the liability and equity components of the Convertible Senior Notes in accordance with authoritative guidance for convertible debt instruments that may be settled in cash upon conversion. The guidance requires the carrying amount of the liability component to be estimated by measuring the fair value of a similar liability that does not have an associated conversion feature. Because the Company had no outstanding non-convertible public debt, the Company determined that senior, unsecured corporate bonds traded on the market represent a similar liability to the Convertible Senior Notes without the conversion option. Based on market data available for publicly traded, senior, unsecured corporate bonds issued by companies in the same industry with similar credit ratings and with similar maturity, the Company estimated the implied interest rate of its Convertible Senior

Notes to be 6.9%, assuming no conversion option. Assumptions used in the estimate represent what market participants would use in pricing the liability component, which were defined as Level 2 observable inputs. The estimated implied interest rate was applied to the Convertible Senior Notes, which resulted in a fair value of the liability component of $141.9 million upon issuance, calculated as the present value of implied future payments based on the $172.5 million aggregate principal amount. The $30.7 million difference between the cash proceeds of $172.5 million and the estimated fair value of the liability component was recorded in additional paid-in capital, net of tax and issuance costs, as the Convertible Senior Notes were not considered redeemable.

During the fourth quarter of 2018, the last reported sales price of the Company's common stock was greater than 130% of the Convertible Senior Notes conversion price for 20 or more of the 30 consecutive trading days preceding the quarter-end. Consequently, the Convertible Senior Notes were convertible as of December 31, 2018. If the Convertible Senior Notes were converted as of December 31, 2018, the if-converted amount would exceed the principal by $1.6 million. The Convertible Senior Notes may be settled at the Company's option in cash or a combination of cash and shares of common stock. Because the settlement could be in cash, the Convertible Senior Notes have been classified as short-term debt as of December 31, 2018.

During the year ended December 31, 2018, the Company entered into separate, privately negotiated exchange agreements with certain holders of the notes. In addition, certain note holders requested conversion and the Company elected to issue shares of common stock in exchange for the notes. To measure the resulting loss as of the settlement dates, the applicable interest rates were estimated using Level 2 observable inputs and applied to the converted notes using the same methodology as in the issuance date valuation. The following table summarizes information about the settlement of the Convertible Senior Notes (in thousands):

	Year ended December 30, 2018
Principal amount settled	$ 108,811
Number of shares of common stock issued	3,699
Loss on extinguishment of debt	$ 2,303

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,	
	2018	2017
Principal amount of Convertible Senior Notes outstanding	$58,503	$167,314
Unamortized discount of liability component	(3,637)	(15,356)
Unamortized deferred issuance costs	(487)	(2,090)
Net carrying amount of liability component	54,379	149,868
Less: current portion	54,379	—
Long-term debt	$—	$149,868
Carrying value of equity component, net of issuance costs	$10,092	$29,211
Fair value of outstanding Convertible Senior Notes	$85,999	$257,245
Remaining amortization period of discount on the liability component	2 years	3 years

Credit Agreement

On October 6, 2017, the Company entered into a Credit Agreement (the "Credit Agreement"), which provided the Company with a $245.0 million senior secured term loan facility (the "Term Loan") and a $25.0 million Revolving Credit Facility ("Revolving Credit Facility") together (the "Senior Credit Facility"). On the closing date of the Credit Agreement, the Company borrowed the entire amount of the Term Loan and $10.0 million under the Revolving Credit Facility. The Company used the proceeds of the Term Loan along with its cash on hand, to pay (i) the consideration for the Triage Business and (ii) the fees and expenses incurred in connection with the acquisition of the Triage and BNP Businesses.

During the first three quarters of 2018, the Company used cash on hand of $161.8 million to pay down a portion of the existing Term Loan. Separately, the Company also repaid the entire outstanding $10.0 million balance on its Revolving Credit Facility under the Credit Agreement.

On August 31, 2018, the Company entered into an Amended and Restated Credit Agreement to replace the prior Credit Agreement. The Amended and Restated Credit Agreement provides the Company with a $175.0 million Revolving Credit Facility. In connection with the closing of the Amended and Restated Credit Agreement, the Company borrowed $83.2 million under the Revolving Credit Facility to settle the outstanding Term Loan principal of $83.2 million. During the fourth quarter of 2018, Company used cash on hand to repay $30.0 million in principal of

the Revolving Credit Facility. The remaining balance of $53.2 million is due upon maturity on August 31, 2023. Due to the early payments on the Term Loan and the modification of the Credit Facility, the Company recorded losses on extinguishment of debt of $6.0 million during the year ended December 31, 2018.

The Amended and Restated Credit Agreement does not include any term loan component. Loans will bear interest at a rate equal to (i) the London Interbank Offered Rate ("LIBOR") plus the "applicable rate" or (ii) the "base rate" (defined as the highest of (a) the Bank of America prime rate, (b) the Federal Funds rate plus one-half of one percent and (c) LIBOR plus one percent) plus the "applicable rate." The initial applicable rate was 1.00% per annum for base rate loans and 2.00% per annum for LIBOR rate loans, and thereafter will be determined in accordance with a pricing grid based on the Company's Consolidated Leverage Ratio (as defined in the Credit Agreement) ranging from 1.75% to 2.50% per annum for LIBOR rate loans and from 0.75% to 1.50% per annum for base rate loans. In addition, the Company pays a commitment fee on the unused portion of the Credit Agreement based on the Company's Consolidated Leverage Ratio ranging from 0.15% to 0.30% per annum.

The Amended and Restated Credit Agreement is guaranteed by certain material domestic subsidiaries of the Company (the "Guarantors") and is secured by liens on substantially all of the assets of the Company and the Guarantors, excluding real property and certain other types of excluded assets, and contains affirmative and negative covenants that are customary for credit agreements of this nature. The negative covenants include, among other things, limitations on asset sales, mergers, indebtedness, liens, dividends and other distributions, investments and transactions with affiliates. The Amended and Restated Credit Agreement contains two financial covenants: (i) maximum Consolidated Leverage Ratio (as defined in the Amended and Restated Credit Agreement) as of the last day of each fiscal quarter of 3.50 to 1.00, which ratio may be increased to 4.50 to 1.00 in case of certain qualifying acquisitions; and (ii) a minimum Consolidated Fixed Charge Coverage Ratio (as defined in the Amended and Restated Credit Agreement) of 1.25 to 1.00 as of the end of any fiscal quarter for the most recently completed four fiscal quarters. The Company was in compliance with all financial covenants as of December 31, 2018.

Interest expense recognized on the Term Loan and the Revolving Credit Facility for the year ended December 31, 2018 totaled $5.7 million for the stated interest and commitment fee. Amortization of debt issuance costs associated with the Term Loan and the Revolving Credit Facility was $0.8 million for the year ended December 31, 2018, and was recorded to interest expense in the Company's Consolidated Statements of Operations.

Note 4. Income Taxes

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

	December 31,		
	2018	2017	2016
Current:			
Federal	$—	$(615)	$(117)
State	755	314	246
Foreign	6,575	57	84
Total current provision (benefit)	7,330	(244)	213
Deferred:			
Federal	(9,970)	131	(2,545)
State	(7,944)	238	(63)
Foreign	(215)	4	4
Total deferred (benefit) provision	(18,129)	373	(2,604)
(Benefit) provision for income taxes	$(10,799)	$129	$(2,391)

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

	December 31,		
	2018	2017	2016
United States	$46,592	$(8,198)	$(16,426)
Foreign	16,792	162	227
Income (loss) before income taxes	$63,384	$(8,036)	$(16,199)

Significant components of the Company's deferred tax assets and deferred tax liabilities as of December 31, 2018 and 2017 are shown below (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$711	$3,924
Intangible assets	3,502	2,935
Sale-leaseback, net	617	628
Allowance for returns and discounts	4,541	5,358
Stock-based compensation	5,333	5,933
Tax credit carryforwards	12,246	5,247
Other, net	6,883	4,580
Total deferred tax assets	33,833	28,605
Valuation allowance for deferred tax assets	(1,830)	(15,204)
Total deferred tax assets, net of valuation allowance	32,003	13,401
Deferred tax liabilities:		
Convertible Senior Notes	(636)	(3,633)
Intangible assets	(2,165)	(2,935)
Property, plant and equipment	(7,010)	(7,263)
Total deferred tax liabilities	(9,811)	(13,831)
Net deferred tax assets (liabilities)	$22,192	$(430)

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 in prior years was 3 years of cumulative pre-tax book losses. For the three years ended December 31, 2018, however, the Company has demonstrated positive cumulative pre-tax book income. Such objective positive evidence allows the Company to consider other subjective evidence, such as the Company's projections for future profitability, to determine the realizability of its deferred tax assets. On the basis of this evaluation, during the quarter ended December 31, 2018, the Company released $13.4 million of valuation allowance, which is shown as a deferred tax benefit during the period. The Company maintains a valuation allowance of $1.8 million, which represents the portion of the deferred tax asset that management could not conclude was more likely than not to be realized. The amount of the deferred tax assets considered realizable could be adjusted in the future based on changes in available positive and negative evidence.

As of December 31, 2018, the Company had no federal net operating loss ("NOL") carryforwards. The Company had state NOLs of approximately $19.3 million which will begin to expire in 2029, unless previously utilized. The Company has federal research credits of $5.8 million which will begin to expire on December 31, 2032, unless previously utilized. The Company has federal foreign tax credits of $2.4 million which will begin to expire on December 31, 2028 unless previously utilized. The Company has state research credits of $12.8 million, of which $12.4 million do not expire. The remaining $0.4 million begin to expire in 2028, unless previously utilized.

Pursuant to Internal Revenue Code 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. As of December 31, 2018, the Company does not believe any historical ownership change has limited the use of its NOLs or tax credit carryforwards.

The reconciliation of income tax computed at the federal statutory rate to the provision (benefit) for income taxes from continuing operations is as follows (in thousands):

	Year ended December 31,		
	2018	2017	2016
Tax expense (benefit) at statutory tax rate	$13,311	$(2,812)	$(5,775)
State tax (benefits), net of federal tax	1,526	(239)	(390)
Permanent differences	635	327	129
Federal and state research credits—current year	(3,628)	(484)	(979)
Accrual of uncertain tax positions	—	142	43
Stock-based compensation	(9,286)	(5,851)	—
Impact of change in federal and state tax rate on revaluing deferred tax assets	—	3,357	(4)
Change in valuation allowance	(13,374)	5,799	4,687
Foreign Derived Intangible Income Deduction (FDII)	(786)	—	—
Other	803	(110)	(102)
(Benefit) provision for income taxes	$(10,799)	$129	$(2,391)

On December 22, 2017, the Tax Cuts and Jobs Act (the “Tax Act”) was enacted into legislation, which includes a broad range of provisions affecting businesses. The Tax Act significantly revises how companies compute their U.S corporate tax liability by, among other provisions, reducing the corporate tax rate from 35% to 21% for tax years beginning after December 31, 2017, implementing a territorial tax system, and requiring a mandatory one-time tax on U.S. owned undistributed foreign earnings and profits known as the transition tax.

Pursuant to the SEC Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (“SAB 118”), a company may select between one of three scenarios to determine a reasonable estimate arising from the Tax Act. Those scenarios are (i) a final estimate which effectively closes the measurement window; (ii) a reasonable estimate leaving the measurement window open for future revisions; and (iii) no estimate as the law is still being analyzed. The Company was able to provide a reasonable estimate for the provisional revaluation of deferred taxes and the effects of the transition tax on undistributed foreign earnings and profits for the period ended December 31, 2017. During the quarter ended December 31, 2018 the Company completed its accounting for the impacts of the Tax Act.

Additionally, the Company has elected to treat global intangible low taxed income (GILTI) as a period cost and will expense GILTI in the period it is incurred. Because of the Company’s current operational structure, there is minimal expected GILTI impacts for the year ended December 31, 2018 and future years.

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

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

	Year ended December 31,		
	2018	2017	2016
Beginning balance	$9,565	$8,604	$7,684
(Decreases) increases related to prior year tax positions	(558)	10	(10)
Increases related to current year tax positions	6,238	951	773
Other	—	—	157
Ending balance	$15,245	$9,565	$8,604

As of December 31, 2018 and 2017, the unrecognized tax benefits of $15.2 million and $9.6 million, respectively, of which $9.3 million and $8.1 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 the income tax provision. The Company has accrued approximately $0.3 million of interest and penalties associated with uncertain tax positions as of the years December 31, 2018 and 2017. Interest expense, net of accrued interest (reversed), was approximately $0.1 million for both of the years ended December 31, 2018 and 2017. There was no interest expense, net of accrued interest (reversed) in 2016.

The Company is subject to periodic audits by domestic and foreign tax authorities; however, there are no known audits at this time. 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 5. 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, 2018, 2017 or 2016.

Equity Incentive Plan. The Company grants stock options, time-based restricted stock units ("RSUs") and performance-based restricted stock units ("PSUs") to employees and non-employee directors under its 2018 Equity Incentive Plan (the "2018 Plan"). The Company previously granted stock options under its 2016 Equity Incentive Plan (the "2016 Plan"), Amended and Restated 2010 Equity Incentive Plan (the "2010 Plan") and the Amended and Restated 2001 Equity Incentive Plan (the "2001 Plan"). The 2016 Plan, 2010 Plan and 2001 Plan were terminated at the time of adoption of the 2018 Plan, but the terminated Plans continue to govern outstanding options granted thereunder. The Company has stock options, RSUs and PSUs 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 $10.25 to $53.27 per share, and generally vest over four years. As of December 31, 2018, approximately 3.2 million shares remained available for grant under the 2018 Plan.

Restricted Stock Units. The Company grants both RSUs and PSUs to certain officers, directors and management. Until the restrictions lapse, ownership of the affected restricted stock units granted to the Company's officers, directors and management is conditional upon continuous employment with the Company.

For the years ended December 31, 2018, 2017 and 2016, the Company granted approximately 0.2 million, 0.3 million and 0.7 million shares, respectively, of RSUs to Board of Directors, officers and management, which either have a time-based four-year vesting provision or performance-based vesting provisions.

During the years ended December 31, 2018 and 2016, RSUs were granted to certain members of the Board of Directors in lieu of cash compensation as a part of the Company's non-employee director's deferred compensation program. During the year ended December 31, 2017, common stock was issued to certain members of the Board of Directors in lieu of cash compensation for these members that elected to participate and agree to hold the stock for the elected deferral period. The compensation expense associated with these RSU grants were $0.4 million, $0.1 million and $0.4 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Employee Deferred Bonus Compensation Program. For the year ended December 31, 2017, the deferred bonus compensation program was suspended temporarily by the Board of Directors. For the years ended December 31, 2018 and 2016, certain employees of the Company were eligible to participate in the Company's deferred bonus compensation program with respect to any payments received under the Company's cash incentive plan. Participating employees could elect to receive 50% or 100% of the cash value of their cash bonus in the form of fully vested, restricted stock units plus an additional premium as additional restricted stock units, issued under the 2016 Plan or 2018 Plan. The premium restricted stock units are subject to a one-year vesting requirement from the date of issuance. The additional premium will be determined based on the length of time of the deferral period selected by the

participating employee as follows: (i) if one year from the date of grant, a premium of 10% on the amount deferred, (ii) if two years from the date of grant, a premium of 20% on the amount deferred, or (iii) if four years from the date of grant, a premium of 30% on the amount deferred.

Employee Stock Purchase Plan. Under the Company's Amended and Restated 1983 Employee Stock Purchase Plan (the "ESPP"), full-time employees are allowed to purchase common stock through payroll deductions (which cannot exceed 10% of the employee's compensation) at the lower of 85% of fair market value at the beginning or end of each six-month purchase period. As of December 31, 2018, 1,321,456 shares had been sold under the Plan, leaving 178,544 shares available for future issuance.

Share Repurchase Program. On January 25, 2016, the Company's Board of Directors authorized an amendment to extend the previously announced stock repurchase program. The Board of Directors has authorized the Company to repurchase up to an aggregate of $50.0 million in shares of our common stock under our stock repurchase program. Any shares of common stock repurchased under this program will no longer be deemed outstanding upon repurchase and will be returned to the pool of authorized shares. During the year ended December 31, 2016, 1,152,386 shares of outstanding common stock were repurchased under the Company's previously announced share repurchase program for approximately $19.6 million. There were no repurchases during 2017 and this repurchase program expired on January 25, 2018. On December 12, 2018, the Board of Directors authorized a new stock repurchase program, pursuant to which up to $50.0 million of the Company's shares of common stock may be purchased through December 12, 2020. There were no repurchases during 2018 and at December 31, 2018, $50.0 million remained available under the new repurchase program.

Shares Reserved for Future Issuance. At December 31, 2018, approximately 5.7 million shares of common stock were reserved under the Company's equity incentive plan and 178,544 shares were reserved for purchases under the ESPP.

Note 6. Stock-Based Compensation

For the years ended December 31, 2018, 2017 and 2016 stock-based compensation expense was $11.7 million, $9.1 million and $8.0 million, respectively, of which $3.4 million, $4.1 million and $4.7 million, respectively, related to stock options and $6.7 million, $4.9 million and $2.4 million, respectively, related to restricted stock units. For the years ended December 31, 2018, 2017 and 2016, the Company recorded $1.6 million, $0.1 million and $0.9 million in stock-based compensation expense, respectively, associated with the deferred bonus compensation program, described in Note 5. During the years ended December 31, 2018 and 2016, $1.6 million and $0.9 million, respectively, was initially recorded as a component of accrued payroll and related expenses. Since the employee Deferred Bonus Compensation Program was suspended in 2017, there was no component of stock-based compensation recorded to accrued payroll related expenses during the year ended December 31, 2017.

Stock-based compensation expense related to stock options and restricted stock units was as follows (in thousands):

	Year ended December 31,		
	2018	2017	2016
Cost of sales	$763	$579	$617
Research and development	2,266	1,886	1,551
Sales and marketing	2,843	2,129	1,189
General and administrative	5,837	4,467	4,629
Total stock-based compensation expense	$11,709	$9,061	$7,986

Stock-based compensation expense capitalized to inventory and compensation expense related to the Company's ESPP were not material for the years ended December 31, 2018, 2017 and 2016.

Stock Options

Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option award. The estimated fair value of each stock option was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions:

	Year ended December 31,		
	2018	2017	2016
Risk-free interest rate	2.49%	2.30%	1.47%
Expected option life (in years)	6.29	6.63	6.59
Volatility rate	36 %	36 %	36 %
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 $18.76, $8.99 and $6.00 for options granted during the years ended December 31, 2018, 2017 and 2016, respectively. The total intrinsic value was $38.2 million, $26.8 million and $4.5 million for options exercised during the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, total unrecognized compensation expense related to stock options was approximately $4.4 million and the related weighted-average period over which it is expected to be recognized is approximately 1.7 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, 2016, 2017 and 2018 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, 2016	3,967	$ 17.44		
Granted	677	15.48		
Exercised	(553)	13.76		
Cancelled	(150)	20.86		
Outstanding at December 31, 2016	3,941	17.49		
Granted	263	22.21		
Exercised	(1,527)	16.38		
Cancelled	(18)	24.91		
Outstanding at December 31, 2017	2,659	18.54		
Granted	159	46.50		
Exercised	(891)	17.07		
Cancelled	(50)	21.19		
Outstanding at December 31, 2018	1,877	$ 21.53	5.98	$ 49,976
Vested and expected to vest at December 31, 2018	1,838	$ 21.34	5.93	$ 49,302
Exercisable at December 31, 2018	1,117	$ 19.28	4.83	$ 32,374

Restricted Stock Units

The Company grants both time-based restricted stock units (“RSUs”) and performance-based restricted stock units (“PSUs”). The fair value of RSUs and PSUs is determined based on the closing market price of the Company’s common stock

on the grant date. Compensation expense for RSUs is measured at the grant date and recognized ratably over the vesting period. A portion of the restricted stock granted in 2018 and 2017 is performance-based and vesting is tied to achievement of specific Company goals over a three-year time period, subject to early vesting upon achievement of the performance goals. For purposes of measuring compensation expense for PSUs, the number of shares ultimately expected to vest is estimated at each reporting date based on management's expectations regarding the relevant performance criteria. There was no stock-based compensation expense related to PSUs for the year ended December 31, 2016.

A summary of the status of restricted stock unit activity for the years ended December 31, 2016, 2017 and 2018 is as follows (in thousands, except price data):

	Shares	Weighted-average grant date fair value
Non-vested at January 1, 2016	459	$ 21.61
Granted	185	16.14
Vested	(120)	18.50
Forfeited	(23)	20.80
Non-vested at December 31, 2016	501	20.37
Granted	349	22.34
Vested	(100)	23.49
Forfeited	(4)	18.69
Non-vested at December 31, 2017	746	20.88
Granted	242	49.97
Vested	(296)	21.70
Forfeited	(16)	28.40
Non-vested at December 31, 2018	676	$ 30.75

Since the employee Deferred Bonus Compensation Program was suspended in 2017, there were no restricted stock units issued in exchanged for the deferred bonus liability in 2018. In 2017 and 2016, the Company issued approximately 0.1 million restricted stock units each year in exchange for the deferred bonus liability of $0.9 million and $0.5 million, respectively.

The total amount of unrecognized compensation expense related to non-vested restricted stock units as of December 31, 2018 was approximately $12.1 million, which is expected to be recognized over a weighted-average period of approximately 2.1 years.

Note 7. Earnings (Loss) Per Share

Basic earnings (loss) per share ("EPS") is computed by dividing net income (loss) by the weighted-average number of common shares outstanding. Diluted EPS is computed based on the sum of the weighted average number of common shares and potentially dilutive common shares outstanding during the period. Potentially dilutive common shares consist of shares issuable from stock options, unvested RSUs and the 3.25% Convertible Senior Notes. Potentially dilutive common shares from outstanding stock options and unvested RSUs are determined using the average share price for each period under the treasury stock method. Potentially dilutive shares from the Convertible Senior Notes are determined using the if-converted method. Under the provisions of the if-converted method, the Convertible Senior Notes are assumed to be converted and the resulting commons shares are included in the denominator of the EPS calculation and the interest expense, net of tax, recorded in connection with the Convertible Senior Notes is added back to net income (loss).

The Convertible Senior Notes have a dilutive impact when the average market price of the Company's common stock exceeds the applicable conversion price of the notes. The Convertible Senior Notes became convertible on March 31, 2018 and remained convertible through December 31, 2018.

The following table reconciles net income (loss) and the weighted-average shares used in computing basic and diluted earnings per share in the respective periods (in thousands):

	Twelve months ended December 31,		
	2018	2017	2016
Numerator:			
Net income (loss) used for basic earnings per share	$74,183	$(8,165)	$(13,808)
Interest expense on Convertible Senior Notes, net of tax	4,927	—	—
Net income (loss) used for diluted earnings per share, if-converted method	$79,110	$(8,165)	$(13,808)
Basic weighted-average common shares outstanding	37,995	33,734	32,708
Potentially dilutive shares issuable from Convertible Senior Notes, if-converted	2,850	—	—
Potentially dilutive shares issuable from stock options and unvested RSUs	1,709	—	—
Diluted weighted-average common shares outstanding, if-converted	42,554	33,734	32,708
Potentially dilutive shares excluded from calculation due to anti-dilutive effect	161	37	2,770

Potentially dilutive shares excluded from the calculation above represent stock options when the combined exercise price and unrecognized stock-based compensation are greater than the average market price for the Company's common stock because their effect is anti-dilutive.

The number of potentially dilutive shares issuable under the Convertible Senior Notes that would have been included in the diluted EPS calculation if the Company had earnings amounted to 1.4 million for the year ended December 31, 2017. Stock options and RSUs that would have been included in the diluted EPS calculation if the Company had earnings amounted to 1.4 million and 0.8 million for the years ended December 31, 2017 and 2016. No conversion premium existed on the Convertible Senior Notes as of December 31, 2016; therefore, there was no dilutive impact from the Convertible Senior Notes to diluted EPS during the year ended December 31, 2016.

Note 8. Commitments and Contingencies

Leases

The Company leases its facilities and certain equipment. Commitments for minimum rentals under non-cancelable leases at the end of 2018 are as follows (in thousands):

Years ending December 31,	Operating Leases	Lease obligation
2019	$9,940	$ 956
2020	10,601	967
2021	10,502	—
2022	8,965	—
2023	8,409	—
Thereafter	86,797	—
Total minimum lease payments	$135,214	$ 1,923

Operating Leases—Rent expense under operating leases totaled approximately $10.2 million for the year ended December 31, 2018, $2.1 million for the year ended December 31, 2017 and $2.2 million for the year ended December 31, 2016.

On January 5, 2018, the Company entered into a sale and leaseback transaction for the San Diego property on Summers Ridge Road (the "Summers Ridge Property") that was acquired as part of the Triage Business from Alere discussed in Note 12. The Summers Ridge Property was included as assets held for sale on the Consolidated Balance Sheet as of December 31, 2017. The Company sold the Summers Ridge Property for a net consideration of $146.6 million. In addition, the Company entered into a lease agreement with the buyer to lease two of the four buildings on the Summers Ridge Property for an initial term of 15 years. The Summers Ridge lease is subject to certain must-take provisions related to two additional buildings, consisting of approximately 125,000 square feet, upon the expiration of certain leases with the tenants of the other portion of the Summers Ridge Property. The initial term can be extended by the Company for two additional 5-year terms upon satisfaction of certain conditions. The future minimum lease payments above excludes one building for which the must-take clause has not been triggered.

McKellar Court Lease Obligation—During 1999, the Company completed a sale and leaseback transaction of its San Diego facility at McKellar Court. 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 for the McKellar Court property, which had no significant impact on the Company's financial statements. The amended terms included a new ten-year lease term through December 31, 2019, with options to extend the lease for up to three additional five-year periods. In the fourth quarter of 2015, the Company amended the terms of its lease agreement to extend the lease term through December 31, 2020. The options to extend the lease for up to three additional five-year periods commence at the new lease term date of December 31, 2020. The Company is amortizing the lease obligation over the new estimated lease term, including extensions. As the Company accounts for the lease as a financing transaction, the Company adjusted the implied interest rate so that the existing lease obligation is amortized to the end of the estimated lease term, including extensions. The Company has determined that the partnership is a variable interest entity (VIE). The Company is not, however, the primary beneficiary of the VIE as it does not absorb the majority of the partnership's expected losses or receive a majority of the partnership's residual returns. The Company made lease payments to the partnership of approximately $0.9 million for each of the years ended December 31, 2018, 2017 and 2016, respectively.

Purchase Commitments

The Company has $9.1 million in firm inventory purchase commitments as of December 31, 2018, the majority of which will be purchased within the next twelve months.

Litigation and Other Legal Proceedings

In Beckman Coulter Inc. v. Quidel Corporation, which was filed in the Superior Court for the County of San Diego, California (the "Trial Court"), on November 27, 2017, Beckman Coulter Inc. ("Beckman") alleges that a provision of an agreement between Quidel and Beckman violates state antitrust laws. Our acquisition of the BNP Business consisted of assets and liabilities relating to a contractual arrangement with Beckman (the "Beckman Agreement") for the supply of antibodies and other inputs related to, and distribution of, the Triage® BNP Test for the Beckman Coulter Access Family of Immunoassay Systems. The Beckman Agreement further provides that Beckman, for a specified period, cannot research or develop an assay for use in the diagnosis of cardiac diseases that measures or detects the presence or absence of BNP or NT-pro-BNP (a related biomarker). In the lawsuit, Beckman asserts that this provision violates certain California antitrust laws and is unenforceable. Beckman contends that it has suffered damages due to this provision and seeks a declaration that this provision is void.

On December 7, 2018, the Trial Court granted Beckman's motion for summary adjudication of its first cause of action for declaratory relief (the "Order"), finding the challenged provision void under California law. On December 18, 2018, the Trial Court stayed the effect of the Order pending our petitioning the Fourth District Court of Appeal (the "Court of Appeal") for a stay and review of the Order.

On January 18, 2019, we filed a petition for writ of mandate with the Court of Appeal, seeking immediate appellate review of the Order and requesting a stay of the Order pending review. Beckman requested and obtained an extension to file a preliminary opposition to the writ petition, which is due on February 25, 2019. We intend to file a reply to the preliminary opposition, which will be due twenty days after the filing of the opposition.

On February 7, 2019, the Trial Court stayed the remaining litigation on Beckman's second cause of action pending a decision from the Court of Appeal on whether they will hear the merits of our writ petition. The Trial Court also vacated all deadlines in the case, including the trial date. The parties are to report back to the Trial Court once the Court of Appeal issues its decision on whether to review the merits of our writ petition.

We continue to deny that the contractual provision is unlawful, deny any liability with respect to this matter, and intend to continue to vigorously defend ourselves. There are multiple factors that prevent us from being able to estimate the amount of loss, if any, that may result from this matter including: (1) we are vigorously defending ourselves and believe that we have a number of meritorious legal defenses; (2) there are unresolved questions of law and fact that could be important to the ultimate resolution of this matter; and (3) discovery is in the very early stages. Accordingly, at this time, we are not able to estimate a possible loss or range of loss that may result from this matter or to determine whether such loss, if any, would have a material adverse effect on our financial condition, results of operations or liquidity.

From time to time, the Company is involved in other litigation and proceedings, including matters related to product liability claims, commercial disputes and intellectual property claims, as well as regulatory, employment, and other claims related to our business. The Company accrues for legal claims when, and to the extent that, amounts associated with the claims become probable and are reasonably estimable. The actual costs of resolving legal claims may be substantially higher or lower than the amounts accrued for those claims. For those matters as to which we are not able to estimate a possible loss or range of loss, we are not able to determine whether the loss will have a material adverse effect on our business, financial condition or results of operations or liquidity. No accrual has been recorded as of December 31, 2018 and December 31, 2017 related to such matters as they are not probable and/or reasonably estimable.

Management believes that all such current legal actions, in the aggregate, will not have a material adverse effect on the Company. However, the resolution of, or increase in any accruals for, one or more matters may have a material adverse effect on the Company's results of operations and cash flows.

The Company also maintains insurance, including coverage for product liability claims, in amounts which management believes are appropriate given the nature of its business.

Licensing Arrangements

The Company has entered into various licensing and royalty agreements, which largely require payments by the Company 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 $0.4 million, $0.6 million and $0.8 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Note 9. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented 32%, 18% and 17% of total revenue for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018 and 2017, balances due from foreign customers were $23.4 million and $18.8 million, respectively.

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

	Year ended December 31,		
	2018	2017	2016
Customer:			
A	19%	20%	15%
B	13%	13%	13%
C	12%	21%	16%
	44%	54%	44%

As of December 31, 2018 and 2017, accounts receivable from individual customers with balances due in excess of 10% of total accounts receivable totaled $33.3 million and $44.4 million, respectively.

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

	Long-lived assets as of December 31,		Total revenue for the years ended December 31,		
	2018	2017	2018	2017	2016
Domestic	$ 72,569	$ 59,833	$354,895	$227,611	$158,244

Foreign	1,332	1,752	167,390	50,132	33,359
Total	$ 73,901	$ 61,585	$522,285	$277,743	$191,603

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

	Year ended December 31,		
	2018	2017	2016
Rapid Immunoassay	$183,160	$165,099	$121,416
Cardiac Immunoassay	266,524	47,030	—
Specialized Diagnostic Solutions	53,243	51,978	60,681
Molecular Diagnostic Solutions	19,358	13,636	9,506
Total revenues	$522,285	$277,743	$191,603

Note 10. 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, 2018				December 31, 2017			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Contingent consideration	$—	$—	$19,112	$19,112	$—	$—	$24,301	$24,301
Deferred consideration	—	187,158	—	187,158	—	223,158	—	223,158
Total liabilities measured at fair value	$—	$187,158	$19,112	$206,270	$—	$223,158	$24,301	$247,459

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, 2018 and 2017.

In connection with the acquisition of the BNP Business, the Company will pay up to $280.0 million in cash, of which $256.0 million is guaranteed and is considered deferred consideration and $24.0 million is contingent consideration. The fair value of the deferred consideration was determined to be $220.6 million on the acquisition date based on the net present value of cash payments using an estimated borrowing rate using a quoted price for a similar liability. The Company recorded $10.0 million for the accretion of interest on the deferred consideration in 2018. The fair value of contingent consideration on the acquisition date was $19.7 million and was calculated using a discounted probability weighted valuation model.

Contingent consideration related to the acquisitions of BioHelix Corporation in May 2013, AnDiaTec GmbH & Co. KG in August 2013 and Immutopics, Inc. in March 2016, was $4.6 million as of December 31, 2017. During the year ended December 31, 2018, the Company fully paid the BioHelix Corporation and AndiaTec GmbH & Co. KG related contingent consideration and the Immutopics, Inc. related contingent consideration of $0.3 million remained as of December 31, 2018.

The Company assesses the fair value of contingent consideration to be settled in cash related to these prior acquisitions using a discounted revenue model. Significant assumptions used in the measurement include revenue projections and discount rates. This fair value measurement of contingent consideration is based on significant inputs not observed in the market and thus represent Level 3 measurements. Due to changes in the estimated payments and a shorter discounting period related to the various contingent consideration liabilities, the fair value of the contingent consideration changed during the years ended 2018, 2017 and 2016. These changes resulted in loss of $1.1 million for 2018 recorded to general and administrative expenses in the Consolidated Statements of Operations and gains of $0.1 million and $0.5 million for the years 2017 and 2016, respectively, recorded to cost of sales in the Consolidated Statements of Operations.

Changes in estimated fair value of contingent consideration liabilities from December 31, 2017 through December 31, 2018 are as follows (in thousands):

	Contingent consideration liability (Level 3 measurement)

Balance at December 31, 2017	$ 24,301
Cash payments	(6,303)
Net loss recorded for fair value adjustments	1,114
Balance at December 31, 2018	$ 19,112

Note 11. 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 $2.6 million, $1.5 million and $1.5 million to the 401(k) Plan during the years ended December 31, 2018, 2017 and 2016, respectively.

Note 12. Acquisition

On October 6, 2017, the Company closed on the acquisition of the Triage and BNP Businesses. The acquisition was accounted for in conformity with ASC Topic 805, Business Combinations. In connection with the acquisition of the Triage Business, the Company paid $399.8 million in cash and assumed certain liabilities. These acquisitions enhance the Company's revenue profile and expand the Company's geographic footprint and product diversity. The Company used proceeds from the Term Loan (defined and discussed in Note 3) of $245.0 million and cash on hand to pay (i) the consideration for the Triage Business and (ii) fees and expenses incurred in connection with the acquisition of the Triage and BNP Businesses. In connection with the acquisition of the BNP Business, the Company: (i) will pay (A) $16.0 million in cash plus up to an additional $24.0 million in contingent consideration, payable in five annual installments of up to $8.0 million, the first of which was due and paid on April 2018, (B) $240.0 million in cash, payable in six annual installments of $40.0 million each, the first of which was due and paid in April 2018 and (C) $0.2 million in cash for certain inventory related adjustments; and (ii) assumed certain liabilities.

The purchase price consideration is as follows (in thousands):

Cash consideration—Triage Business	$399,798
Deferred consideration—BNP Business	220,550
Contingent consideration—BNP Business	19,700
Inventory related adjustment	205
Net consideration	$640,253

The fair value of the deferred consideration was determined to be $220.6 million on the acquisition date based on the net present value of cash payments. The discount rate utilized was based on a quoted borrowing rate for a similar liability. The fair value of contingent consideration on the acquisition date of $19.7 million was calculated using a discounted probability weighted valuation model.

The components of the purchase price allocation at the acquisition date is as follows:

Prepaid expenses and other current assets	$796
Assets held for sale	146,540
Inventories	52,205
Property, plant and equipment	10,608
Intangible assets	184,900
Goodwill	245,531
Other non-current assets	182
Total assets acquired	640,762
Other current liabilities	(509)
Total net assets and liabilities acquired	$640,253

Goodwill represents the excess of the total purchase price over the fair value of the underlying net assets, largely arising from synergies expected to be achieved by the combined Company and the expanded revenue profile and product diversity. The goodwill is fully deductible for tax purposes.

The fair value of the identified intangible assets was determined primarily using an income-based approach. Intangible assets are amortized on a straight-line basis over the respective amortization periods. The following sets forth results of the amounts assigned to the identifiable intangible assets acquired (in thousands):

Intangible Asset	Amortization period	Fair value of assets acquired
Purchased technology	10 years	$52,400
Customer relationships	7 years	115,000
Trademarks	10 years	17,500
Total intangible assets		$184,900

Note 13. Selected Quarterly Financial Data (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
2018				
Total revenues	$169,143	$ 103,155	$ 117,399	$ 132,588
Gross profit	$106,271	$ 57,668	$ 69,642	$ 82,132
Operating income (loss)	$51,093	$ 404	$ 16,894	$ 27,538
Net income (loss)	$33,958	$ (3,076)	$ 10,822	$ 32,479
Basic income (loss) per share	$0.96	$ (0.08)	$ 0.28	$ 0.82
Diluted income (loss) per share	$0.86	$ (0.08)	$ 0.27	$ 0.78
2017				
Total revenues	$73,692	$ 38,267	$ 50,894	$ 114,890
Gross profit (1)	$48,499	$ 18,826	$ 29,690	$ 59,127
Operating income (loss)	$19,229	$ (11,027)	$ (2,537)	$ 3,887
Net income (loss)	$14,290	$ (11,842)	$ (5,525)	$ (5,088)
Basic income (loss) per share	$0.43	$ (0.35)	$ (0.16)	$ (0.15)
Diluted income (loss) per share	$0.42	$ (0.35)	$ (0.16)	$ (0.15)

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, 2018:				
Accounts receivable allowance	$12,309	$ 65,142	$ (65,472)	$ 11,979
Year ended December 31, 2017:				
Accounts receivable allowance	$7,165	$ 36,449	$ (31,305)	$ 12,309
Year ended December 31, 2016:				
Accounts receivable allowance	$7,488	$ 28,329	$ (28,652)	$ 7,165

(1) Represents charges associated primarily to accruals for early payment 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, 2018 at a reasonable assurance level 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 quarter ended December 31, 2018 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, 2018.

The effectiveness of our internal control over financial reporting as of December 31, 2018 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

To the Shareholders and the Board of Directors of Quidel Corporation

Opinion on Internal Control over Financial Reporting

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2018, and the related notes and schedule listed in the Index at Item 15(a)(2) and our report dated February 15, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

San Diego, California

February 15, 2019

80

Item 9B. Other Information

2019 Annual Meeting of Stockholders

The Company’s 2019 Annual Meeting of Stockholders will be held on Tuesday, May 14, 2019, 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 is incorporated by reference to our 2019 proxy statement, which will be filed with the SEC no later than April 30, 2019 (the "2019 Proxy Statement"). Information with respect to the Company's executive officers is included under Part 1 of this Annual Report.

Item 11. Executive Compensation

The information required by this item is incorporated by reference from our 2019 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 our 2019 Proxy Statement.

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

The information required by this item is incorporated by reference from our 2019 Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference from our 2019 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, 2018, 2017 and 2016 is filed as part of this Annual Report in Part II, Item 8 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 this Item 15 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 8-K filed on February 27, 2015.)
3.2	Certificate of Amendment to the Restated Certificate of Incorporation of Quidel Corporation, effective as of May 5, 2015. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on May 6, 2015.)
3.3	Amended and Restated Bylaws of Quidel Corporation. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on February 27, 2015.)
4.1	Certificate of Designations of Series C Junior Participating Preferred Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on 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 Registration Statement on 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 14, 2016.)
10.2(1)	Registrant's Amended and Restated 2018 Equity Incentive Plan. (Incorporated by reference to Appendix A to the Registrant's Proxy Statement filed on April 12, 2018.)
10.3(1)	Form of Notice of Grant of Award and Award Agreement for Registrant's 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.)
10.4(1)	Form of Restricted Stock Award Agreement for Registrant's 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.)
10.5(1)	Registrant's 2016 Equity Incentive Plan. (Incorporated by reference to Appendix A to the Registrant's Proxy Statement filed on April 14, 2016.)
10.6(1)	Form of Notice of Grant of Stock Options and Option Award Agreement for Registrant's 2016 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016.)

10.7(1)	Form of Restricted Stock Unit Award Grant Notice for Registrant's 2016 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.8 to the Registrant’s Annual Report on Form 10-K for the year ended December 31, 2016.)
10.8(1)	Form of Restricted Stock Unit Award Grant Notice (Deferred Compensation) for Registrant’s 2016 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.9 to the Registrant’s Annual Report on Form 10-K for the year ended December 31, 2016.)
10.9(1)	Form of Restricted Stock Unit Award Terms and Conditions for Registrant’s 2016 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.10 to the Registrant’s Annual Report on Form 10-K for the year ended December 31, 2016.)
10.10	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.)
10.11	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.)
10.12	Third Amendment to Single Tenant Absolute Net Lease. (Incorporated by reference to Exhibit 10.10 to Registrant’s Annual Report on Form 10-K filed for the year ended December 31, 2015.)

10.13(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.)
10.14(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.)
10.15(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.)
10.16(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.)
10.17(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.)
10.18(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.)
10.19(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.)
10.20(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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2014.)
10.21(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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2014.)
10.22(1)	Employment Offer Letter, dated December 19, 2014, between the Registrant and Michael D. Abney, Jr. (Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015.)
10.23(1)	Agreement Re: Change in Control, entered into on January 19, 2015, between the Registrant and Michael D. Abney, Jr. (Incorporated by reference to Exhibit 10.7 to the Registrant's Form 10-Q for the quarter ended March 31, 2015.)
10.24(1)	Employment Offer Letter, dated October 4, 2015, between the Registrant and Edward K. Russell. (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015.)
10.25(1)	Agreement Re: Change in Control, entered into on October 12, 2015, between the Registrant and Edward Russell. (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015.)
10.26	Amended and Restated Triage Purchase Agreement, dated September 15, 2017 (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on October 6, 2017.)

10.27	Amended and Restated BNP Purchase Agreement, dated September 15, 2017 (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on October 6, 2017.)
10.28	Summers Ridge Lease (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 9, 2018.)
10.29(1)	Employment Offer Letter, dated October 16, 2017, between the Registrant and Ratan S. Borkar. (Incorporated by reference to Exhibit 10.33 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2017.)
10.30(1)	Agreement Re: Change in Control, entered into on October 16, 2017, between the Registrant and Ratan S. Borkar. (Incorporated by reference to Exhibit 10.34 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2017.)
10.31(1)	2018 Cash Incentive Compensation Plan (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 22, 2018.)
10.32(1)	2018 Annual Equity Incentive Plan Grants to the Registrant's Executive Officers. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on January 22, 2018.)
10.33	Exchange Agreement, dated March 8, 2018. (Incorporated by reference to Exhibit 10.1 to of the Registrant's Form 8-K filed on March 9, 2018.)

10.34	Exchange Agreement, dated May 31, 2018. (Incorporated by reference to Exhibit 10.1 to of the Registrant's Form 8-K filed on June 1, 2018.)
10.35	Amended and Restated Credit Agreement, by and among Company, as Borrower, Bank of America, N.A. as Administrative Agent, Swing Line Lender and L/C Issuer, JPMorgan Chase Bank, N.A., as Syndication Agent, Bank Of America Merrill Lynch and JP Morgan Chase Bank, N.A., as Joint Lead Arrangers and Joint Lead Bookrunners, dated as of August 31, 2018. (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018.)
10.36(1)*	Form of Restricted Stock Unit Award Grant Notice (2018 Equity Incentive Plan)
10.37(1)*	Form of Restricted Stock Unit Award Grant Notice (Performance Based) (2018 Equity Incentive Plan)
10.38(1)*	Form of Restricted Stock Unit Award Grant Notice (Time Based) (2018 Equity Incentive Plan)
10.39(1)*	Form of Notice of Grant of Nonqualified Stock Options and Option Agreement (2018 Equity Incentive Plan)
10.40(1)*	Form of Restricted Stock Unit Award Grant Notice (Deferred) (2018 Equity Incentive Plan)
10.41(1)	2019 Cash Incentive Compensation Plan (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on February 6, 2019.)
10.42(2)	2019 Annual Equity Incentive Plan Grants to the Registrant's Executive Officers. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on February 6, 2019.)
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.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Label Linkbase Document

101.PRE* XBRL Taxonomy Presentation Linkbase Document
*Filed / furnished herewith
(1)Indicates a management plan or compensatory plan or arrangement.

Item 16. Form 10-K Summary
Not applicable.

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
Date: February 15, 2019 President, Chief Executive Officer
(Principal Executive Officer)

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	Director, President, Chief Executive Officer (Principal Executive Officer)	February 15, 2019
/s/ RANDALL J. STEWARD Randall J. Steward	Chief Financial Officer, (Principal Financial and Accounting Officer)	February 15, 2019
/s/ KENNETH F. BUECHLER Kenneth F. Buechler	Chairman of the Board	February 15, 2019
/s/ THOMAS D. BROWN Thomas D. Brown	Director	February 15, 2019
/s/ EDWARD L. MICHAEL Edward L. Michael	Director	February 15, 2019
/s/ MARY LAKE POLAN Mary Lake Polan	Director	February 15, 2019
/s/ JACK W. SCHULER Jack W. Schuler	Director	February 15, 2019
/s/ CHARLES P. SLACIK Charles P. Slacik	Director	February 15, 2019
/s/ MATTHEW W. STROBECK Matthew W. Strobeck	Director	February 15, 2019
/s/ KENNETH J. WIDDER Kenneth J. Widder	Director	February 15, 2019