QUIDEL CORP /DE/
Form 424B5
December 01, 2014
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The information in this prospectus supplement is not complete and may be changed. This prospectus supplement and the accompanying prospectus are not an offer to sell these securities and are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion

Preliminary Prospectus Supplement dated December 1, 2014

PROSPECTUS SUPPLEMENT

(To prospectus dated December 1, 2014)

$150,000,000

% Convertible Senior Notes due 2020

We are offering $150 million aggregate principal amount of % Convertible Senior Notes due 2020. We will pay interest on the notes on June 15 and December 15 of each year, beginning June 15, 2015. The notes will mature on December 15, 2020, unless earlier repurchased by us or converted.

Holders may convert their notes at any time prior to the close of business on the business day immediately preceding September 15, 2020 only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2015, if the closing sale price of our 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 for the notes for each such trading day was less than 98% of the closing sale price of our common stock on such date multiplied by the then-current conversion rate; or (3) upon the occurrence of specified corporate events. 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. Upon conversion, we will

pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election, as described in this prospectus supplement.

The initial conversion rate will be shares of our common stock for each $1,000 principal amount of notes, which represents an initial conversion price of approximately $ per share. Following certain corporate transactions that occur on or prior to the stated maturity date, we will increase the conversion rate for a holder that elects to convert its notes in connection with such a corporate transaction.

We may not redeem the notes prior to maturity. No sinking fund is provided for the notes.

If a fundamental change, as defined herein, occurs prior to the stated maturity date, holders may require us to purchase for cash all or any portion of their notes at a fundamental change purchase price equal to 100% of the principal amount of the notes to be purchased, plus accrued and unpaid interest to, but excluding, the fundamental change purchase date.

We do not intend to apply to list the notes on any securities exchange or for inclusion of the notes on any automated dealer quotation system. Our common stock is listed on The NASDAQ Global Select Market under the ticker symbol QDEL. On November 28, 2014, the closing sale price of our common stock was $27.86 per share.

Investing in the notes involves risks that are described in the Risk Factors section beginning on page S-14 of this prospectus supplement.

	Per Note	Total
Public offering price (1)	%	$
Underwriting discount	%	$
Proceeds, before expenses, to us (1)	%	$

(1) Plus accrued interest from December , 2014, if settlement occurs after that date.

The underwriters may exercise their right to purchase up to an additional $22,500,000 principal amount of the notes for 30 days after the date of this prospectus supplement, solely to cover over-allotments.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The notes will be ready for delivery in book-entry only form through the facilities of The Depository Trust Company for the accounts of its participants on or about December , 2014.

BofA Merrill Lynch **J.P. Morgan**

The date of this prospectus supplement is December , 2014.

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Prospectus Supplement

Prospectus

We have not, and the underwriters have not, authorized anyone to give any information or make any other representation about us that is different from or in addition to, that contained in this prospectus supplement or the accompanying prospectus, including any information incorporated by reference in this prospectus supplement or the accompanying prospectus, or in any free writing prospectus prepared or authorized by us. Therefore, if anyone does give you information of this sort, you should not rely on it as authorized by us. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. Neither the delivery of this prospectus supplement or the accompanying prospectus or the documents incorporated by reference in this prospectus supplement or the accompanying prospectus or any free writing prospectus, nor any sale made

hereunder, shall under any circumstances create any implication that there has been no change in our affairs since the date hereof or that the information incorporated by reference herein is correct as of any time subsequent to the date of such information. Our business, financial condition, results of operations and prospects may have changed since those dates.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the Securities and Exchange Commission (the SEC), using a shelf registration process. This prospectus supplement provides you with the specific details regarding this offering of notes and updates the information contained or incorporated by reference in the accompanying prospectus. The accompanying prospectus provides you with more general information regarding our securities, some of which does not apply to the offering. You should read and consider both this prospectus supplement and the accompanying prospectus together with the additional information described under the headings Where You Can Find Additional Information and Incorporation of Certain Information by Reference in this prospectus supplement and the accompanying prospectus. To the extent the information set forth in this prospectus supplement differs in any way from the information set forth in the accompanying prospectus or the information contained in any document incorporated by reference therein, the information contained in the most recently dated document shall apply.

This prospectus supplement is not a prospectus for the purposes of the EU s Directive 2003/71/EC (the PD) and has been prepared on the basis that any offer of notes in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of notes. Accordingly any person making or intending to make an offer in that Relevant Member State of notes which are the subject of the offering contemplated in this prospectus supplement may only do so in circumstances in which no obligation arises for the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the underwriters have authorized, nor do they authorize, the making of any offer of notes in circumstances in which an obligation arises for the Company or the underwriters to publish a prospectus for such offer.

In the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who (i) have professional experience in matters relating to investments and falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the Order), (ii) who are high net worth companies falling within Article 49(2)(a) to (d) of the Order, or (iii) persons to whom it may otherwise be lawfully communicated) pursuant to the Order (all such persons together being referred to as relevant persons). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and the accompanying prospectus contain or incorporate forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act) that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, fluctuations in our operating results resulting from seasonality; the timing of the onset, length and severity of cold and flu seasons; government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses; adverse changes in competitive conditions in domestic and international markets; the reimbursement system currently in place and future changes to that system; changes in economic conditions in our domestic and international markets; changes in sales levels as it relates to the absorption of our fixed costs; lower than anticipated market penetration of our products; the quantity of our product in our distributors inventory or distribution channels; changes in the buying patterns of our distributors; changes in the health care market and consolidation of our customer base; our development and protection of intellectual property; our development of new technologies, products and markets; our reliance on a limited number of key distributors; our reliance on sales of our influenza diagnostics tests; our ability to manage our growth strategy, including our ability to integrate companies or technologies we have acquired or may acquire; intellectual property risks, including but not limited to, infringement litigation; limitations and covenants in our senior credit facility; that we may incur significant additional indebtedness; our need for additional funds to finance our operating needs; volatility and disruption in the global capital and credit markets; acceptance of our products among physicians and other healthcare providers; competition with other providers of diagnostic products; adverse actions or delays in new product reviews or related to currently-marketed products by the U.S. Food and Drug Administration (the FDA); changes in government policies; compliance with other government regulations, such as safe working conditions, manufacturing practices, environmental protection, fire hazard and disposal of hazardous substances; third-party reimbursement policies; our ability to meet demand for our products; interruptions in our supply of raw materials; product defects; business risks not covered by insurance and exposure to other litigation claims; interruption to our computer systems; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, exposure to currency exchange fluctuations and foreign currency exchange risk sharing arrangements, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, political and economic instability, taxes, and diversion of lower priced international products into US markets; volatility in our stock price; dilution resulting from future sales of our equity; and provisions in our charter documents and Delaware law that might delay stockholder actions with respect to business combinations or the election of directors.

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 forwa statements are expressed differently. Forward-looking statements in or incorporated into this prospectus supplement and the accompanying prospectus include, among others, statements concerning: the use of proceeds of this offering; our outlook for the fiscal years ended December 31, 2014 and 2015, including projections about our revenue, gross margins, expenses cash flow, EBITDA, COGS, market opportunities, geographic expansion and development, manufacturing and commercial activities; projected capital expenditures for the upcoming fiscal year, including the components thereof, and our source of funds for such expenditures; the sufficiency of our liquidity and capital resources; our strategy, goals and objectives; that point-of-care testing is increasing; that we will continue to make substantial expenditures for research and development activities; our reliance on key distributors; that influenza test revenues will continue to be a significant portion of our total revenue; industry consolidation and competition trends;

competition for management and key personnel; that we may enter into additional foreign currency exchange risk sharing arrangements; that the price of our common stock will continue to fluctuate; our exposure to claims and

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litigation; our intention to not pay dividends; expectations regarding grant revenues and expenditures in 2014 and 2015; that we will continue to incur substantial royalty and license expenses; the exposure of money market assets to market fluctuation risk; expected savings from the move of certain manufacturing operations to our Athens, Ohio facility; the impact on our tax rate due to changes in California law; and our intention to continue to evaluate technology and acquisition opportunities.

The risks described under Risk Factors in this prospectus supplement and the accompanying prospectus, together with all of the other documents contained or incorporated by reference in this prospectus supplement and the accompanying prospectus, and in other reports that we file with the SEC from time to time, should be carefully considered. You are cautioned not to place undue reliance on forward-looking statements, which reflect management s expectations only as of the date made. 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.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information contained elsewhere or incorporated by reference in this prospectus supplement. This summary does not contain all of the information that you should consider before investing in the notes. You should read the entire prospectus supplement and the accompanying prospectus carefully, including Risk Factors, the financial statements and related footnotes thereto and other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus before making an investment decision. This prospectus supplement, the accompanying prospectus and the documents incorporated by reference contain forward-looking statements that involve risks and uncertainties. See Special Note Regarding Forward-Looking Statements.

Unless the context otherwise requires (i) all information in this prospectus supplement assumes that the underwriters do not exercise their over-allotment option to purchase additional notes, and (ii) any reference to Quidel, the Company, we, us and our in this prospectus supplement refers to Quidel Corporation and its subsidiaries.

The Company

Overview

We have a leadership position in the development, manufacturing and marketing of rapid diagnostic testing solutions. These diagnostic testing solutions primarily include applications in infectious diseases, women s health and gastrointestinal diseases. We sell our products directly to end users and distributors, in each case, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, leading universities, retail clinics and wellness screening centers. We market our products in the United States through a network of national and regional distributors, and a direct sales force. Internationally, we sell and market primarily through distributor arrangements.

We commenced our operations in 1979 and launched our first products, dipstick-based pregnancy tests, in 1983. Since such time, our product base and technology platforms have expanded through internal development and acquisitions of other products, technologies and companies. Our diagnostic solutions aid in the detection and diagnosis of many critical diseases and other medical conditions, including infectious diseases, women s health, autoimmune diseases, bone health, thyroid diseases, and fecal occult blood. In February 2010, we expanded our operations through the acquisition of Diagnostic Hybrids, Inc. (DHI), a privately-held, in vitro diagnostics (IVD) company, based in Athens, Ohio. DHI is a market leader in the manufacturing and commercialization of FDA cleared direct fluorescent IVD assays used in hospitals and reference laboratories for a variety of diseases, including certain viral infections and thyroid diseases. In 2013, we completed two further acquisitions, acquiring the stock of BioHelix Corporation (BioHelix), a developer and manufacturer of isothermal molecular assays and enzymes, in May 2013, and acquiring the assets of AnDiaTec GmbH (AnDiaTec), a German based developer and manufacturer of molecular assays, in August 2013.

Business Strategy

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

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

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

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

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

Our current initiatives to execute this strategy include the following:

- continue to focus our research and development efforts on three areas:
  - new proprietary product platform development;
  - the creation of improved products and new products for existing markets and unmet clinical needs, and
  - pursuit of collaborations with, or acquisitions of, other companies for new and existing products and markets that advance our differentiated strategy;
- provide clinicians with validated studies that encompass the clinical efficacy and economic efficiency of our diagnostic tests for the professional market;

continue to focus on strengthening our market and brand leadership in infectious diseases and women s health by acquiring and/or developing and introducing clinically superior diagnostic solutions;

strengthen our direct sales force to create direct relationships with integrated delivery networks, laboratories and hospitals, with a goal of driving growth through improved physician and laboratorian satisfaction;

support payer evaluation of diagnostic tests and establishment of favorable reimbursement rates;

continue to create strong global alliances to support our efforts to achieve leadership in key markets and expand our presence in emerging markets; and

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- further refine our manufacturing efficiencies and productivity improvements to improve profit, with continued focus on profitable products and markets and our effort to create a core competency in new product development.

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

The Overall Market for *In Vitro* Diagnostics

Customers for IVD products are primarily centralized laboratories and physician offices and other decentralized non-institutional settings.

Centralized testing market

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

Decentralized POC market

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

- Hospital POC testing is accepted and growing and is generally an extension of the hospital s central laboratory. Hospitals in the U.S. have progressively sought to reduce the length of patient stays and, consequently, the proportion of cases seen as outpatients have increased. If the U.S. experience is representative of future trends, emergency departments and other critical care units such as intensive care units, operating rooms, trauma and cardiac centers are increasingly becoming the principal centers for the management of moderate and severe acute illness.

- Out-of-hospital testing sites consist of physicians office laboratories, nursing homes, pharmacies, retail clinics and other non-institutional, ambulatory settings in which healthcare providers perform diagnostic tests.

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

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

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Products

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

System Platforms New and In Development:

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

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

Molecular assays

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

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

Molecular Systems in Development.

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

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

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Medical and Wellness Categories:

Our products address the following medical and wellness categories:

Infectious Diseases

Influenza. Our Sofia® Influenza A+B test, used in conjunction with our *Sofia®M Analyzer,* and our QuickVue® influenza tests are rapid, qualitative tests for the detection of the viral antigens of influenza type A and B, the two most common types of the influenza virus. In addition, our Sofia® Influenza A+B test has special 510(k) clearance for an update to our package insert to include analytical reactivity with an avian Influenza A (H7N9) strain, A/Anhui/1/2013. In addition, during 2013, we began selling our Quidel Molecular Influenza A+B assay for use on the QuantStudio Dx Real-Time PCR Instruments by Life Technologies.

Streptococci. Our Sofia® Strep A fluorescent immunoassay, used in conjunction with our *Sofia®M* Analyzer, and our QuickVue® Strep A tests are intended for the rapid, qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture. Also, in late 2013, we began selling our AmpliVue Group B Strep Assay. In 2014, we began selling our AmpliVue Group A Strep Assays. In 2014, we also received FDA clearance, via the *de novo* request procedure, for our *Lyra* Direct Strep Assay, a multiplex real-time PCR assay that detects and differentiates between pyogenic Group A and pyogenic C or G Streptococcal throat infections.

RSV Test. Our Sofia® RSV test and our QuickVue® RSV test are rapid immunoassay tests for Respiratory Syncytial Virus (RSV). During 2013, we also began selling our Quidel Molecular RSV + human metapneumovirus (hMPV) test, and our Quidel Molecular Influenza A+B assay and our combo Quidel Molecular RSV + hMPV assay, both for use on the QuantStudio Dx Real-Time PCR Instruments by Life Technologies. The majority of upper respiratory tract infections in children are caused by viruses and RSV is generally recognized as a frequent agent responsible for these infections.

Multiplex Respiratory. Our cell culture and DFA detection solutions are used by reference laboratories, public health labs and acute care hospitals to detect seven major viral respiratory pathogens. Our proprietary cell culture platform R-Mix™ combined with our FDA cleared antibody kit D^{3}®UltraTM DFA, detects Influenza A and B, RSV, Adenovirus and Parainfluenza types 1, 2 and 3, with turn-around times between 16 and 48 hours. The same D^{3}® Ultra DFATM antibody kit can also be used for direct specimen testing for those viruses with turn-around times in less than 90 minutes. In 2009, we introduced a new FDA cleared technology called D^{3}® FastPointTM that detects eight viruses, with human metapnuemovirus added to the testing menu. D^{3}® FastPointTM provides laboratories, in a direct specimen testing format, the ability to produce virus identification in less than 25 minutes from specimen receipt.

In 2014, we began commercializing our *Lyra* Adenovirus Assay, a real-time PCR test for the qualitative detection of human adenovirus (HAdV) viral DNA, and our *Lyra* Parainfluenza Assay, a real-time PCR test for the qualitative detection and identification of Parainfluenza virus infections for types 1, 2 or 3 viral RNA.

General Virology. We provide a wide variety of traditional cell lines, specimen collection devices, media and controls for use in laboratories that culture and test for normal human viruses. We provide cell-based products under the FreshCells™ brand in multiple different formats, including tubes, shell vials and multi-well plates.

Herpes and Herpes Family. Our proprietary engineered cell culture system, ELVIS® HSV, is an FDA cleared and highly sensitive system for the isolation and detection of Herpes Simplex Virus (HSV) types 1 and 2. Herpes is a widespread sexually transmitted infection with an HSV 2 prevalence rate of 16% of the population according to the

Centers for Disease Control (CDC). We also provide a multiplex cell culture solution using a

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propriety cell platform called H&V-Mix ™ that is used to isolate HSV, Varicella-Zoster Virus (VZV) and Cytomegalovirus, all in the herpes family of viruses. Antibody detection and identification of each of these viruses can be performed with FDA cleared antibody products provided under the D3® DFA brand. During 2014, we also began commercializing our Lyra Direct HSV 1+2/VZV assay and AmpliVue HSV 1+2 for the differentiation and detection of herpes simplex viruses 1 and 2 (HSV 1+2) and Varicella-Zoster Virus in active lesions within the United States.

Clostridium difficile (*C. diff*). Our Quidel Molecular Direct *C. diff* assay is approved for use with the Life Technologies QuantStudio Dx and 7500 Fast Dx Applied Biosystems Real-Time PCR Instruments. We also sell our *C. diff* assay as part of our expanding AmpliVue® product line. C. *diff* is a life threatening bacterial infection, especially for the elderly and patients on a prolonged antibiotic regimen. Currently more than 500,000 cases of C. *diff* infections are diagnosed each year in the U.S.

POC Women s Health

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

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

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

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

Gastrointestinal Diseases

Immunoassay fecal occult blood. Our QuickVue® test is a rapid, fecal immunochemical test (FIT) intended to detect the presence of blood in stool specimens. Blood in the stool is an indication of a number of gastrointestinal disorders, including colorectal cancer. We launched our first FIT test in late December 2005.

Enterovirus. Enteroviruses reproduce initially in the gastrointestinal tract before spreading to other organs such as the nervous system, heart and skin. Enteroviruses can also infect the respiratory tract.

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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 D^3 IFA Enterovirus kit are used by reference laboratories and acute care hospitals.

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

Bone Health, Autoimmune Disease and Oncology

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

Corporate Information

We are incorporated in the State of Delaware. Our executive offices are located at 12544 High Bluff Drive, Suite 200, San Diego, California 92130, our telephone number is (858) 552-1100, and our website is www.quidel.com. Our website, and the information contained therein, is not a part of this prospectus supplement.

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THE OFFERING

The following summary is provided solely for your convenience and is not intended to be complete. You should read the full text and more specific details contained elsewhere in this prospectus supplement and the accompanying prospectus. In this section, references to Quidel, we, us or our refer to Quidel Corporation and not to any of its subsidiaries.

Issuer	Quidel Corporation, a Delaware corporation.
Securities Offered	$150,000,000 aggregate principal amount of % Convertible Senior Notes due 2020 (*plus* up to an additional $22,500,000 principal amount at the underwriters option, solely to cover over-allotments).
Maturity	December 15, 2020, unless earlier purchased or converted.
Interest	% per year, payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2015. We will pay additional interest, if any, at our election as the sole remedy relating to the failure to comply with our reporting obligations as described under Description of the Notes Events of Default.
Ranking	The notes will be our senior unsecured obligations and will be: • senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the notes; • equal in right of payment to our existing and future unsecured indebtedness that is not so subordinated; • effectively junior to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and • structurally junior to all existing and future indebtedness (including trade payables) incurred by our subsidiaries.

	We are party to a senior credit facility pursuant to which we may borrow up to $140.0 million. As of the date of this prospectus supplement, we do not have any outstanding indebtedness under the senior credit facility. The senior credit facility is secured by all of our assets and the assets of our subsidiaries that are guarantors of our obligations under the senior credit facility, including our and their intellectual property.
No Redemption	We may not redeem the notes prior to maturity and no sinking fund will be provided for the notes.

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Conversion	Holders may surrender their notes for conversion at any time prior to the close of business on the business day immediately preceding September 15, 2020 only under the following circumstances: during any calendar quarter commencing after the calendar quarter ending on March 31, 2015 (and only during such calendar quarter), if the closing sale price of our 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; 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 notes for each such trading day is less than 98% of the closing sale price of our common stock on such date *multiplied by* the then-current conversion rate; or upon the occurrence of specified corporate events described under Description of the Notes Conversion of Notes Conversion upon Specified Corporate Transactions. 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 regardless of the foregoing circumstances. The initial conversion rate for the notes will be shares of our common stock for each $1,000 principal amount of notes (equivalent to an initial conversion price of approximately $ per share of our common stock). Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. If we satisfy our conversion obligation in solely cash or a combination of cash and shares of our common stock, the amount of cash and shares of common stock, if any, due upon conversion will be based on a daily conversion value (as described herein) calculated for each trading day in a 25 trading day conversion period (as described herein). See Description of the Notes Conversion of Notes Settlement upon Conversion.

Holders will not receive any additional cash payment or additional shares of our common stock representing accrued and unpaid interest, if any, upon conversion of a note, except in limited circumstances. Instead, interest will be deemed to be paid by the consideration delivered to you upon conversion of a note. As a result, accrued and unpaid interest, if any, to, but not including, the conversion date will be deemed to be paid in full rather than cancelled, extinguished or forfeited.

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	The conversion rate for the notes is subject to adjustment as described under Description of the Notes Conversion of Notes Conversion Rate Adjustments and Adjustment to Conversion Rate upon Conversion in Connection with a Make-Whole Fundamental Change.
Purchase of Notes at Your Option upon a Fundamental Change	Holders may require us to purchase for cash all or any portion of their notes upon the occurrence of a fundamental change at the fundamental change purchase price equal to 100% of the principal amount of the notes being purchased, plus accrued and unpaid interest to, but excluding, the fundamental change purchase date. For the definition of fundamental change and related information, see Description of the Notes Purchase of Notes at Your Option upon a Fundamental Change.
Use of Proceeds	We estimate that the net proceeds from this offering, after deducting estimated expenses payable by us and the underwriters discount, will be approximately $ (or approximately $ million if the underwriters exercise their over-allotment option in full). We intend to use the net proceeds from this offering for working capital and other general corporate purposes, which may include acquisitions of products, technologies or businesses, and opportunistic repurchases of shares of our common stock. See Use of Proceeds.
Form and denomination	The notes will be issued only in denominations of $1,000 and in integral multiples of $1,000.
Trading	We do not intend to apply to list the notes on any securities exchange or for inclusion of the notes on any automated dealer quotation system. Our common stock is listed on The NASDAQ Global Select Market under the ticker symbol QDEL.
Risk Factors	See the information under the caption Risk Factors in this prospectus supplement and the other information contained or incorporated by reference in this prospectus supplement for a discussion of factors you should carefully consider before deciding to invest in the notes.
Certain U.S. Federal Income Tax Considerations	See Certain U.S. Federal Income Tax Considerations. You should consult your tax advisor with respect to the United States federal income tax consequences of owning the notes and any common stock into which the notes may be converted in light of your own particular situation and with respect to any tax consequences arising under the laws of any state,

	local, foreign or other taxing jurisdiction.
Governing Law	The notes and the indenture will be governed by the laws of the State of New York.

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Trustee, Paying Agent and Conversion Agent	The Bank of New York Mellon Trust Company, N.A.
Global Securities; Book-Entry Form	The notes will be issued in book-entry form and will be represented by one or more global securities deposited with, or on behalf of, The Depository Trust Company (DTC) and registered in the name of a nominee of DTC. Beneficial interests in any of the notes will be shown on, and transfers will be effected only through, records maintained by DTC or its nominee and any such interest may not be exchanged for certificated securities, except in limited circumstances.

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SUMMARY HISTORICAL CONSOLIDATED FINANCIAL DATA

The following summary consolidated financial information as of and for each of the three years in the period ended December 31, 2013 is derived from our audited consolidated financial statements. The summary consolidated financial information as of and for the nine months ended September 30, 2014 and 2013 is derived from our unaudited consolidated financial statements. Operating results for the nine months ended September 30, 2014 are not necessarily indicative of results that may be expected for the full fiscal year. Each of our fiscal quarters ends on the Sunday closest to the end of the calendar quarter. For ease of reference, the calendar quarter end dates are used herein.

The following data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements, related notes and other financial information included in our Quarterly Report on Form 10-Q for the nine months ended September 30, 2014 and our Annual Report on Form 10-K for the year ended December 31, 2013, each of which is incorporated herein by reference. See Where You Can Find Additional Information.

Consolidated Statements of Operations

	Nine Months Ended September 30,		Year ended December 31,		
	2014	2013[1][2]	2013[1][2]	2012[2]	2011[2]
	(unaudited)				
	(in thousands, except per share data)				
Total revenues	$ 119,018	$ 125,240	$ 175,410	$ 155,741	$ 158,603
Costs and expenses					
Cost of sales (excludes amortization of intangible assets)[3]	52,917	48,297	66,976	61,285	62,865
Research and development	28,714	22,896	34,186	27,716	26,325
Sales and marketing	30,380	24,162	33,829	30,319	25,751
General and administrative	18,949	18,828	25,581	19,800	21,989
Amortization of intangible assets from acquired businesses and technology	6,623	5,957	8,171	6,935	7,124
Impairment loss	3,558				
Facility restructuring		493	1,825		
Total costs and expenses	141,141	120,633	170,568	146,055	144,054
Operating income (loss)	(22,123)	4,607	4,842	9,686	14,549
Other (expense) income					
Interest income	7	15	15	41	203
Interest expense	(1,036)	(1,072)	(1,454)	(2,086)	(2,892)
Other income (expense)	74	(27)	31	(30)	(376)
Total other expense	(955)	(1,084)	(1,408)	(2,075)	(3,065)
Income (loss) before (benefit) provision for taxes	(23,078)	3,523	3,434	7,611	11,484

(Benefit) provision for income taxes	(8,891)	(2,728)	(3,956)	2,618	3,851
Net income (loss)	$ (14,187)	$ 6,251	$ 7,390	$ 4,993	$ 7,633
Basic earnings (loss) per share	$ (0.41)	$ 0.18	$ 0.22	$ 0.15	$ 0.23
Diluted earnings (loss) per share	$ (0.41)	$ 0.18	$ 0.21	$ 0.15	$ 0.23
Shares used in basic per share calculation	34,340	33,774	33,836	33,068	32,903
Shares used in diluted per share calculation	34,340	34,834	34,947	33,702	33,320

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Consolidated Balance Sheet Data

	At September 30,		At December 31,		
	2014	2013	2013	2012	2011
			(in thousands)		
Cash, cash equivalents and marketable securities	$ 17,365	$ 10,248	$ 8,388	$ 14,856	$ 61,332
Working capital	$ 58,599	$ 49,350	$ 54,610	$ 52,271	$ 71,452
Total assets	$ 267,737	$ 265,520	$ 271,485	$ 242,099	$ 278,894
Long-term debt and lease obligations	$ 4,750	$ 5,242	$ 5,126	$ 10,567	$ 47,947
Stockholders equity	$ 217,374	$ 217,661	$ 223,779	$ 199,780	$ 185,386
Shares of common stock outstanding	34,404	33,950	34,073	33,451	33,276

(1) Includes the results of operations of BioHelix and AnDiaTec from dates of acquisition, May 6, 2013 and August 26, 2013, respectively.
(2) Includes reclassification from general and administrative to interest expense of $509 for the nine months ended September 30, 2013, $677 for 2013, $840 for 2012, and $809 for 2011 to conform to current year presentation.
(3) Excludes amortization of intangible assets of $6,079, $5,753 and $6,667 for the years ended December 31, 2013, 2012 and 2011, respectively, and $4,713 and $4,496 for the nine months ended September 30, 2014 and 2013, respectively.

RATIO OF EARNINGS TO FIXED CHARGES

The following table sets forth our ratio of earnings to fixed charges for the periods indicated:

	Nine Months Ended September 30,	Year Ended December 31,				
	2014	2013	2012	2011	2010	2009
Ratio[1]	[2]	2.56x	3.76x	4.29x	[2]	32.42x

(1) For purposes of computing the ratio of earnings to fixed charges, earnings consist of income, including distributions received from equity investments, before income taxes, interest expensed, interest amortized to cost of sales and income attributable to minority interests. Fixed charges consist of interest incurred, whether expensed or capitalized, including amortization of debt issuance costs, if applicable, and the portion of rent expense deemed to represent interest.
(2) For the nine months ended September 30, 2014 and the year ended December 31, 2010, our earnings were insufficient to cover fixed charges; the amount of additional earnings needed to cover fixed charges for such period was $23,078,000 and $17,420,000, respectively.

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RISK FACTORS

An investment in the notes involves a high degree of risk. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. You should carefully consider the following risk factors, together with all of the other information contained in this prospectus supplement and the accompanying prospectus or incorporated by reference into this prospectus supplement and the accompanying prospectus. The risks and uncertainties described below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business. See Special Note Regarding Forward-Looking Statements. If any of the risks discussed below actually occur, our business, financial condition, operating results or prospects could be materially adversely affected. This could cause the value of the notes to decline, and you may lose all or part of your investment. Please note that additional risks not presently foreseen by us or that we currently deem immaterial may also impair our business and operations.

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; in addition, such fluctuations may necessitate us to take a valuation allowance against our deferred tax assets.

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

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

- seasonal fluctuations in our sales of infectious disease tests, which are generally highest in fall and winter, thus resulting in generally lower operating results in the second and third calendar quarters and higher operating results in the first and fourth calendar quarters;

- timing of the onset, length and severity of the cold and flu seasons;

- government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses, such as H1N1 and avian flu;

- changes in the level of competition, such as would occur if one of our competitors introduced a new, better performing or lower priced product to compete with one of our products;

changes in the reimbursement systems or reimbursement amounts that end-users rely upon in choosing to use our products;

changes in economic conditions in our domestic and international markets, such as economic downturns, decreased healthcare spending, reduced consumer demand, inflation and currency fluctuations; changes in government laws and regulations affecting our business;

lower than anticipated market penetration of our new or more recently introduced products;

significant quantities of our product or that of our competitors in our distributors inventories or distribution channels;

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changes in distributor buying patterns; and

changes in the health care market including consolidation in our customer base.

Our operating results in the future could also fluctuate if we are required to record a valuation allowance against our deferred tax assets (DTAs) or subsequently determine such allowance is no longer necessary. Our net deferred tax asset balance as of September 30, 2014 was approximately $11.3 million. Our DTAs consist primarily of net operating loss carryforwards, tax credit carryforwards and deductible temporary differences. ASC 740 requires that companies assess whether a valuation allowance should be recorded against their DTAs based on the consideration of all available evidence, using a more likely than not realization standard. In accordance with ASC 740, we evaluate our DTAs each reporting period, including an assessment of our cumulative income or loss over the prior three-year period and future periods, to determine if a valuation allowance is required. A possible significant negative factor in our assessment whether a valuation allowance should be recorded against our DTAs for the year ending December 31, 2014 is that if we have a significant loss this fiscal year, we could have a three-year historical cumulative loss as of the end of the fiscal year. If, based on available information, we determine in any reporting period that it is more likely than not that some portion, or all, of our DTAs will not be realized, then a valuation allowance against the DTAs must be established with a corresponding charge in that reporting period to income tax expense in the statement of operations. If a valuation allowance is required to be established for the year ending December 31, 2014, the related charge could be for the full amount of our net deferred tax asset balance, which is expected to be lower than the balance at September 30, 2014. There can be no assurance that we will not have to take such a charge with respect to our DTAs. If we are required to take such a charge to our DTAs, the valuation allowance will not impact our ability to utilize these DTAs in the future, and to the extent that we subsequently determine that all or a portion of the valuation allowance is no longer necessary, we will recognize an income tax benefit in the reporting period in which such determination is made in connection with the reversal of the valuation allowance. Analysis of our ability to realize our DTAs requires us to apply significant judgment and is inherently subjective because our future results cannot be predicted with certainty. Any charge against our DTAs, or any subsequent reversal of all or a portion of the related valuation allowance, could have a significant impact on our reported results of operations.

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

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

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

We have issued patents both in the U.S. and internationally, with expiration dates ranging from the present through approximately 2030. In addition to our patents in the U.S., we have patents issued in various other countries including, among others, Australia, Canada, Japan and various European countries, including France, Germany, Italy, Spain and the United Kingdom. Additionally, we have patent applications pending in the U.S. and various foreign jurisdictions. These pending patent applications may not result in the issuance of any patents, or if issued, may not have priority over others applications or may not offer meaningful protection against competitors with similar technology or may

not otherwise provide commercial value. Moreover, any patents issued to us may be challenged, invalidated, found unenforceable or circumvented in the future. Third parties can make, use and sell products covered by our patents in any country in which we do not have patent protection.

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We also license the right to use our products to our customers under label licenses that are for research purposes only. These licenses could be contested and, because we cannot monitor all potential unauthorized uses of our products around the world, we might not be aware of an unauthorized use or might not be able to enforce the license restrictions in a cost-effective manner.

Our current and future licenses may not be adequate for the operation of our business. In the future, we expect that we will require or desire additional licenses from other parties in order to refine our products further and to allow us to develop, manufacture and market commercially viable or superior products. We may not be able to obtain licenses for technology patented by others and required to produce our products on commercially reasonable terms, if at all.

To protect or enforce our patent rights, it may be necessary for us to initiate patent litigation proceedings against third parties, such as infringement suits or interference proceedings. These lawsuits would be expensive, take significant time and would divert management s attention from other business concerns. In the event that we seek to enforce any of our patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, and our patent applications at risk of not being issued. Further, these lawsuits may provoke the defendants to assert claims against us. If we pursue any such claim, we cannot assure you that we will prevail in any of such suits or proceedings or that the damages or other remedies awarded to us, if any, will be economically valuable.

In addition to our patents, we rely on confidentiality agreements and other similar arrangements with our employees and other persons who have access to our proprietary and confidential information, together with trade secrets and other common law rights, to protect our proprietary and confidential technology. These agreements and laws may not provide meaningful protection for our proprietary technology in the event of unauthorized use or disclosure of such information or in the event that our competitors independently develop technologies that are substantially equivalent or superior to ours. Moreover, the laws of some foreign jurisdictions may not protect intellectual property rights to the same extent as those in the U.S. In the event of unauthorized use or disclosure of such information, if we encounter difficulties or are otherwise unable to effectively protect our intellectual property rights domestically or in foreign jurisdictions, our business, operating results and financial condition could be materially and adversely affected.

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

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

We expect to incur increased operating expenses as a result of our increased investment in sales and marketing activities, manufacturing scale-up and new product development associated with our efforts to accomplish our business strategies discussed in Prospectus Supplement Summary The Company-Business Strategy . No assurance can be given that we will be successful in implementing our operational, growth and other strategic efforts. In addition, the funds for our strategic development projects have in the past come primarily from our business operations and a working capital line of credit. If our business slows and we become less profitable, and as a result have less money

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

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

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

Although we have many distributor relationships in the U.S., the market is dominated by a small number of these distributors. Four of our distributors, which are considered to be among the market leaders, collectively accounted for approximately 43%, 42%, and 40% of our total revenue for the years ended December 31, 2013, 2012 and 2011, respectively. We had sales to two distributors for whom sales exceeded 10% of total revenue for the year ended December 31, 2013. In addition, we rely on a few key distributors for a majority of our international sales, and expect to continue to do so for the foreseeable future. The loss or termination of our relationship with any of these key distributors could significantly disrupt our business unless suitable alternatives were timely found or lost sales to one distributor are absorbed by another distributor. Finding a suitable alternative to a lost or terminated distributor may pose challenges in our industry s competitive environment, and another suitable distributor may not be found on satisfactory terms, if at all. For instance, some distributors already have exclusive arrangements with our competitors, and others do not have the same level of penetration into our target markets as our existing distributors. If total revenue from these or any of our other significant distributors were to decrease in any material amount in the future or we are not successful in timely transitioning business to new distributors, our business, operating results and financial condition could be materially and adversely affected.

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

Although we continue to diversify our products, a significant percentage of our total revenues still continue to come from a limited number of our product families. In particular, revenues from the sale of our influenza tests represent a significant portion of our total revenues and are expected to remain so in at least the near future. In addition, the gross margins derived from sales of our influenza tests are significantly higher than the gross margins from our other core products. As a result, if sales or revenues of our influenza tests decline for any reason whether as a result of market share loss or price pressure, obsolescence, a mild flu season, regulatory matters or any other reason our operating results would be materially and adversely affected on a disproportionate basis. For the years ended December 31, 2013, 2012 and 2011, sales of our infectious disease products (including influenza test sales) accounted for 73%, 71%, and 71% respectively, of total revenue.

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

Our business strategy contemplates further growth, which is likely to result in expanding the scope of operating and financial systems and the geographical area of our operations, including further expansion outside the U.S., as new products and technologies are developed and commercialized or new geographical markets are entered. Because we have a relatively small executive staff, acquisitions and other future growth may divert management s attention from other aspects of our business, and place a strain on existing management and our operational, financial and management information systems. Furthermore, we may expand into markets in which we have less experience or incur higher costs.

Some of our growth is expected to come from acquisitions of businesses and technologies. However, we cannot be certain that we will be able to identify attractive acquisition targets, obtain financing for acquisitions on satisfactory terms or successfully acquire identified targets. Additionally, we may experience difficulties integrating the operations of companies or technologies that we may acquire, with our own operations, and we

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may not realize our anticipated benefits and cost savings within our expected time frame, or at all. For example, we have recently completed three business acquisitions. In 2010, we acquired DHI and in 2013, we acquired BioHelix and AnDiaTec (collectively, the recent acquisitions). We expect to need to execute a number of tasks in a timely, efficient and successful manner in order to realize the benefits and cost savings of the recent acquisitions, including retaining and assimilating key personnel, managing the regulatory and reimbursement approval processes, intellectual property protection strategies and commercialization activities, creating uniform standards, controls, procedures, policies and information systems, including with respect to disclosure controls and procedures and internal control over financial reporting, and meeting the challenges inherent in efficiently managing an increased number of employees potentially in different geographic locations, including the need to implement appropriate systems, policies, benefits and compliance programs. The recent acquisitions or other acquisitions may subject us to other risks, including unanticipated costs and expenditures, changes in the business, currency risks, potential changes in relationships with strategic partners, potential contractual or intellectual property issues, fluctuations in quarterly results and financial condition as a result of timing of acquisitions and potential accounting charges and write-downs, and potential unknown liabilities associated with the strategic combination and the combined operations. We can give no assurance that we will be able to successfully identify, complete and integrate strategic acquisitions. Should we encounter difficulties in managing these tasks and risks, our growth strategy may suffer and our revenue and profitability could be adversely affected.

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

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

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

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

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

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

Even if licenses to intellectual property rights are available, they can be costly. We have entered into various licensing agreements, which largely require payments based on specified product sales as well as the achievement of specific milestones. Royalty and license expenses under these arrangements collectively totaled $9.0 million, $9.4 million and $10.9 million for the years ended December 31, 2013, 2012 and 2011, respectively. We believe we will continue to incur substantial royalty and license expenses relating to future sales of our products and the achievement of specific milestones.

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

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

On August 10, 2012, we entered into an amended and restated $140.0 million senior secured syndicated credit facility (the Senior Credit Facility), which matures on August 10, 2017. The agreement governing the Senior Credit Facility is subject to certain customary covenants, including among others: limitation on liens; limitation on mergers, consolidations and sales of assets; limitation on debt; limitation on dividends, stock redemptions and the redemption and/or prepayment of other debt; limitation on investments (including loans and advances) and acquisitions; limitation on transactions with affiliates; and limitation on disposition of assets. We

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are also subject to financial covenants which include a funded debt to adjusted earnings before interest, taxes, depreciation and amortization, and stock-based compensation (adjusted EBITDA) ratio (as defined in the Senior Credit Facility) and an interest coverage ratio. The Senior Credit Facility is secured by substantially all of our present and future assets and properties. If we fail to comply with these covenants, our Senior Credit Facility could become due and payable prior to maturity. As of September 30, 2014 we were in compliance with all financial covenants.

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

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

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

The global capital and credit markets have historically experienced a period of unprecedented turmoil and upheaval, characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. federal government. If these conditions recur, it could adversely affect the demand for our products and services and, therefore, reduce purchases by our customers, which would negatively affect our results of operations and financial condition. In addition, interest rate fluctuations, financial market volatility or credit market disruptions may limit our access to capital, and may also negatively affect our customers and our suppliers ability to obtain credit to finance their businesses. As a result, our customers needs and ability to purchase our products or services may decrease, and our suppliers may increase their prices, reduce their output or change their terms of sale. If our customers or suppliers operating and financial performance deteriorates, or if they are unable to make scheduled payments or obtain credit, our customers may not be able to pay, or may delay payment of, accounts receivable owed to us, and our suppliers may restrict credit or impose different payment terms or reduce or terminate production of products they supply to us. Any inability of customers to pay us for our products and services, or any demands by suppliers for different payment terms, may adversely affect our operating results and financial condition. Additionally, both state and federal government sponsored and private payers, as a result of budget deficits or reductions, may seek to reduce their health care expenditures by renegotiating their contracts with us. Any reduction in payments by such government sponsored or private payers may adversely affect our earnings and cash flow. Declining economic conditions may also increase our costs.

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

A large part of our business is based on the sale of rapid POC diagnostic tests that physicians and other healthcare providers can administer in their own facilities without sending samples to central laboratories. Clinical reference laboratories and hospital-based laboratories are significant competitors of ours in connection

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

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

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

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

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

The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities in the U.S., principally the FDA and corresponding state and foreign regulatory agencies. The FDA regulates most of our products, which are currently all Class I or II devices. The U.S. Department of Agriculture regulates our veterinary products. Our future performance depends on, among other matters, if, when and at what cost we will receive regulatory approval for new products. Regulatory review can be a lengthy, expensive and uncertain process, making the timing and costs of clearances and approvals difficult to predict. In addition, certain of our foreign product registrations are owned or controlled by our international distribution partners, such that any change in our arrangement with such partners could result in the loss of or delay in transfer of any such product registrations, thereby interrupting our ability to sell our products in those markets. Our results of operations would be negatively affected by failures or delays in the receipt of regulatory approvals or clearances, the loss of previously received approvals or clearances or the placement of limits on the marketing and use of our products. For example, the FDA

has recently proposed reclassifications of rapid influenza detection devices from Class I to Class II devices. If such reclassifications affected our ability to market one or more of our rapid

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influenza products, our total revenue may be negatively affected. Furthermore, in the ordinary course of business, we must frequently make subjective judgments with respect to compliance with applicable laws and regulations. If regulators subsequently disagree with the manner in which we have sought to comply with these regulations, we could be subjected to substantial civil and criminal penalties, as well as field corrective actions, product recall, seizure or injunction with respect to the sale of our products. The assessment of any civil and criminal penalties against us could severely impair our reputation within the industry and affect our operating results, and any limitation on our ability to manufacture and market our products could also have a material adverse effect on our business.

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

Changes in government policy could have a significant impact on our business by increasing the cost of doing business, affecting our ability to sell our products and negatively impacting our profitability. Such changes could include modifications to existing legislation, such as U.S. tax policy, or entirely new legislation, such as the Affordable Healthcare Act in the U.S. Although we cannot fully predict the many ways that health care reform might affect our business, the law imposes a 2.3% medical device excise tax on certain transactions, including many U.S. sales of medical devices, which will include the majority of our US product sales. This tax took effect January 1, 2013. For the year ended December 31, 2013, we incurred $1.8 million related to the new medical device tax. It is unclear whether and to what extent, if at all, other anticipated developments resulting from health care reform, such as an increase in the number of people with health insurance, may provide us additional revenue to offset this increased tax. If additional revenue does not materialize, or if our efforts to offset the excise tax through spending cuts or other actions are unsuccessful, the increased tax burden will adversely affect our financial performance.

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

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

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

Our research and development and manufacturing activities involve the controlled use of hazardous materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. These regulations include federal statutes commonly known as CERCLA, RCRA and the Clean Water Act. Compliance with these laws and regulations is already expensive. If any governmental authorities were to impose new environmental regulations requiring compliance in addition to that required by existing regulations, or alter their interpretation of the requirements of such regulations, such environmental regulations could impair our research, development or production efforts by imposing additional, and possibly substantial, costs, restrictions or compliance procedures on our business. In addition, because of the nature of the penalties provided for in some of these

environmental regulations, we could be required to pay sizeable fines, penalties or damages in the event of noncompliance with environmental laws. Any environmental

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violation or remediation requirement could also partially or completely shut down our research and manufacturing facilities and operations, which would have a material adverse effect on our business. The risk of accidental contamination or injury from these hazardous materials cannot be completely eliminated and exposure of individuals to these materials could result in substantial fines, penalties or damages that are not covered by insurance.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We utilize complex computer systems, including enterprise resource planning and warehouse management systems, to support our business units. Regular upgrades of our computer hardware and software revisions are necessary. We cannot assure that our systems will meet our future business needs or that upgrades will operate as designed. We cannot assure that there will not be associated excessive costs or disruptions in portions of our business in the course of our maintenance, support and/or upgrade of these systems. In particular, any disruptions, delays or deficiencies in the implementation of our new enterprise resource planning system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

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

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

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

Our products are sold internationally, with the majority of our international sales to our customers in Europe and Asia-Pacific. We currently sell and market our products through distributor organizations and sales agents. Sales to foreign customers accounted for 13%, 14%, and 14% of our total revenue for the years ended December 31, 2013, 2012 and 2011, respectively. Our international sales are subject to inherent economic, political and regulatory risks, which could impact our financial performance, cause interruptions in our current business operations and impede our international growth. These foreign risks include, among others:

- compliance with multiple different registration requirements and new and changing registration requirements, our inability to benefit from registration for our products inasmuch as registrations may be controlled by a distributor, and the difficulty in transitioning our product registrations;

- compliance with complex foreign and U.S. laws and regulations that apply to our international operations, including U.S. laws such as import/export limitations, the Foreign Corrupt Practices Act, and local laws prohibiting corrupt payments to governmental officials, could expose us or our employees to fines and criminal sanctions and damage our reputation;

- tariffs or other barriers as we continue to expand into new countries and geographic regions;

- exposure to currency exchange fluctuations against the U.S. dollar;

- longer payment cycles, generally lower average selling prices and greater difficulty in accounts receivable collection;

- reduced, or lack of, protection for, and enforcement of, intellectual property rights;

- political and economic instability in some of the regions where we currently sell our products or that we may expand into in the future;

potentially adverse tax consequences; and

diversion to the U.S. of our products sold into international markets at lower prices.

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

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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.

Risks Related to the Notes and Our Common Stock

The notes are effectively subordinated to our secured debt and any liabilities of our subsidiaries.

The notes will rank senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the notes; equal in right of payment to our existing and future unsecured indebtedness that is not so subordinated; effectively junior to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all existing and future indebtedness (including trade payables) incurred by our subsidiaries. In the event of our bankruptcy, liquidation, reorganization or other winding up, our assets that secure debt ranking senior or equal in right of payment to the notes will be available to pay obligations on the notes only after the secured debt has been repaid in full. There may not be sufficient assets remaining to pay amounts due on any or all of the notes then outstanding. The indenture governing the notes will not prohibit us from incurring additional senior debt or secured debt, nor will it prohibit any of our subsidiaries from incurring additional liabilities.

We are party to a senior credit facility pursuant to which we may borrow up to $140.0 million. As of the date of this prospectus supplement, we do not have any outstanding indebtedness under the senior credit facility. The senior credit facility is secured by all of our assets, including our intellectual property.

None of our subsidiaries will guarantee our obligations under, or otherwise become obligated to pay any amounts due on, the notes. Our right to receive assets from any of our subsidiaries upon its liquidation or reorganization, and the right of holders of the notes to participate in those assets, is structurally subordinated to claims of that subsidiary s creditors, including trade creditors. The ability of our subsidiaries to pay dividends and make other payments to us may be restricted by, among other things, applicable corporate and other laws and regulations as well as agreements to which our subsidiaries may become a party. Even if we were a creditor of any of our subsidiaries, our rights as a creditor would be subordinate to any security interest in the assets of that subsidiary and any indebtedness of that subsidiary senior to that held by us.

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

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

Recent regulatory actions may adversely affect the trading price and liquidity of the notes.

We expect that investors in, and potential purchasers of, the notes may employ, or seek to employ, an arbitrage strategy with respect to the notes. Investors that employ an arbitrage strategy with respect to the notes typically implement that strategy by selling short the common stock underlying the notes and dynamically adjusting their short

position while they hold the notes. Investors may also implement this hedging strategy by entering into swaps on our common stock in lieu of or in addition to short selling the common stock.

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The SEC and other regulatory and self-regulatory authorities have implemented various rules and may adopt additional rules in the future that may impact those engaging in short selling activity involving equity securities (including our common stock), including Rule 201 of SEC regulation SHO, the Financial Industry Regulatory Authority, Inc. s Limit Up-Limit Down program, market-wide circuit breaker systems that halt trading of stock for certain periods following specific market declines, and rules stemming from the enactment and implementation of the Dodd-Frank Wall Street Reform and Consumer Protection Act. Past regulatory actions, including emergency actions or regulations, have had a significant impact on the trading prices and liquidity of equity-linked instruments. Any governmental action that similarly restricts the ability of investors in, or potential purchasers of, the notes to effect short sales of our common stock could similarly adversely affect the trading price and the liquidity of the notes.

Our stock price has been highly volatile, and volatility in the market price and trading volume of our common stock could adversely impact the trading price of the notes.

The market price of shares of our common stock has been highly volatile and has fluctuated substantially in the past. For example, between January 1, 2013 and November 28, 2014, the closing price of our shares of common stock, as reported by The NASDAQ Global Select Market, has ranged from a low of $11.40 to a high of $31.71. We expect our shares of common stock to continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control.

In addition, the stock market in general, and The NASDAQ Global Select Market and the market for healthcare companies in particular, have experienced significant price and volume fluctuations that, at times, have been unrelated or disproportionate to the operating performance of the relevant companies. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this section, elsewhere in this prospectus supplement or the documents we have incorporated by reference in this prospectus supplement or for reasons unrelated to our operations, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as industry conditions and general financial, economic and political instability. A decrease in the market price of our common stock would likely adversely impact the trading price of the notes. In the past, following periods of volatility in the market price of a company s securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management s attention and resources.

The market price of our common stock could also be affected by possible sales of our common stock by investors who view the notes as a more attractive means of equity participation in us and by hedging or arbitrage trading activity that we expect to develop involving our common stock. This trading activity could, in turn, affect the trading prices of the notes. This may result in greater volatility in the trading price of the notes than would be expected for non-convertible debt securities.

We will continue to have the ability to incur debt, including secured debt, after this offering; if we incur substantial additional debt, these higher levels of debt may affect our operations and our ability to pay the principal of and interest on the notes.

We and our subsidiaries may be able to incur substantial additional debt in the future, subject to the restrictions contained in our debt instruments, some of which new debt may be secured debt. The indenture governing the notes does not restrict our ability to incur additional indebtedness or require us to maintain financial ratios or specified levels of net worth or liquidity.

As of September 30, 2014, we had $39.6 million available under the Senior Credit Facility. Our ability to borrow under the Senior Credit Facility fluctuates from time to time due to, among other factors, our borrowings under the facility and its funded debt to adjusted EBITDA ratio as and when measured under the Senior Credit Facility. As of December 1, 2014, there were no borrowings outstanding under the Senior Credit Facility.

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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 the notes, or any fundamental change purchase price or any cash due upon conversion, and our creditworthiness generally.

The adjustment to the conversion rate for notes converted in connection with a make-whole fundamental change may not adequately compensate you for any lost value of your notes as a result of such transaction.

If a holder elects to convert its notes in connection with a make-whole fundamental change, we will increase the conversion rate by an additional number of shares of our common stock upon conversion in certain circumstances, as described under Description of the Notes Adjustment to Conversion Rate upon Conversion in Connection with a Make-Whole Fundamental Change. While the adjustment to the conversion rate for notes converted in connection with a make-whole fundamental change is designed to compensate you for the lost option value of your notes as a result of such transaction, the increase is only an approximation of such lost value and may not adequately compensate you for such loss. In addition, if the price paid (or deemed to be paid) per share of our common stock in the make-whole fundamental change is greater than $ per share or less than $ per share (in each case, subject to adjustment), no increase in the conversion rate will be made. Moreover, in no event will the conversion rate per $1,000 principal amount of notes as a result of this adjustment exceed shares of common stock, subject to adjustment in Description of the Notes Adjustment to Conversion Rate upon Conversion in Connection with a Make-Whole Fundamental Change.

Our obligation to increase the conversion rate upon the occurrence of a make-whole fundamental change could be considered a penalty, in which case the enforceability thereof would be subject to general principles of reasonableness and equitable remedies.

We may not have the ability to raise the funds necessary to settle conversions of the notes or purchase the notes as required upon a fundamental change, and our existing debt contains, and our future debt may contain, limitations on our ability to pay cash upon conversion or purchase of the notes.

Following a fundamental change as described under Description of the Notes Purchase of Notes at Your Option upon a Fundamental Change, holders of notes will have the right to require us to purchase their notes for cash. Certain fundamental changes and the exercise of any repurchase right of holders upon a fundamental change would result in an event of default under our existing Senior Credit Facility. A fundamental

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change may also constitute an event of default or prepayment under, and result in the acceleration of the maturity of, our other then-existing indebtedness. In addition, upon conversion of the notes, unless we settle our conversion obligation solely in shares of our common stock (other than cash in lieu of any fractional share), we will be required to make cash payments in respect of the notes being surrendered for conversion as described under Description of the Notes Conversion of Notes Settlement upon Conversion. We may, at any time prior to the final settlement method election date, irrevocably elect to satisfy our conversion obligation with respect to each subsequent conversion date in a combination of cash and shares of our common stock, if any, with a particular specified dollar amount (as defined below), in which case we will no longer be permitted to settle the corresponding portion of our conversion obligation in shares of our common stock. We cannot assure you that we will have sufficient financial resources, or will be able to arrange financing, to pay the fundamental change purchase price in cash with respect to any notes surrendered by holders for purchase upon a fundamental change or make cash payments upon conversions. In addition, restrictions in our current or then existing credit facilities or other indebtedness, if any, may not allow us to purchase the notes upon a fundamental change or make cash payments upon conversions of the notes (including, as noted above, restrictions in our existing Senior Credit Facility on the repurchase of notes upon a fundamental change). Our failure to purchase the notes upon a fundamental change or make cash payments upon conversions thereof when required would result in an event of default with respect to the notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or