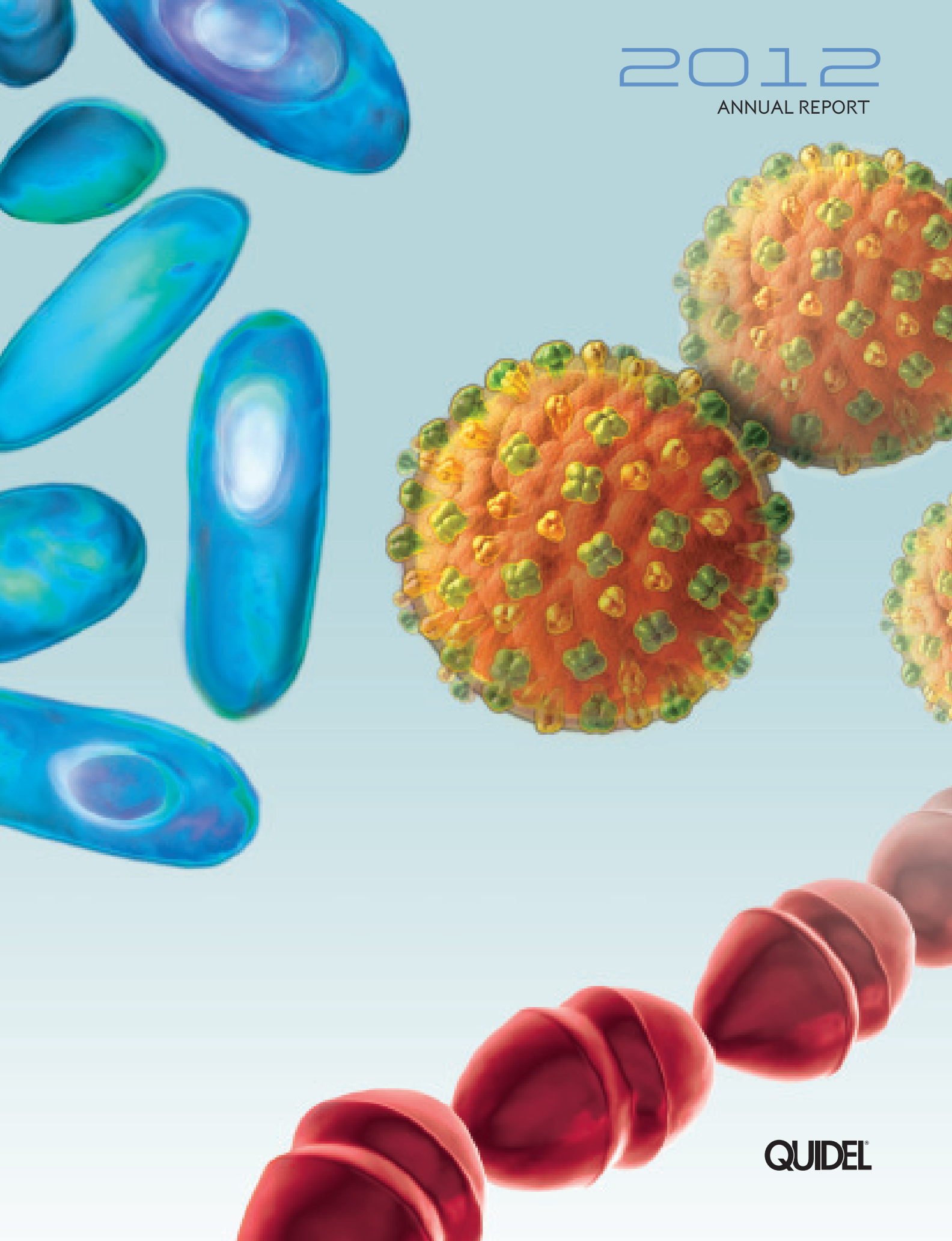
2012
ANNUAL REPORT



QUIDEL®

In the near-term, we expect to introduce other respiratory assays and a qualitative pregnancy test, with the intent of solidifying and potentially expanding our existing served market.

"Our strategy for Sofia has been straightforward and simple, and has now been validated by our early success."

Cover Illustration/Clockwise from the top left: C. difficile virus, Human respiratory syncytial virus and Group A Streptococcus virus.

Dear Fellow Shareholders,

Our company's primary objective is to build a broader-based diagnostic company by developing products and technology platforms that enable us to access larger global markets. We believe that to be successful, we must create products that deliver for our customers one or more key advantages: improved accuracy, quicker time to result, better ease of use, or lower cost. For that reason, each of the platforms and products that are currently in development is expected to deliver more than one of these key attributes.

In 2012, we accomplished several milestones that will contribute to our competitiveness in the fast growing point-of-care and molecular diagnostic segments. By mid-year, we completed the expansion of our U.S. sales organization, and began in earnest the launch of our next generation point-of-care analyzer, Sofia,® and first assay, Sofia Influenza A+B. By the end of the year we had placed over 3,000 Sofia analyzers with customers world-wide, a significant proportion of which were new to our company. In addition, our R&D and regulatory teams made advancements across a number of development programs, with approximately 50% of resources devoted to Sofia and 50% to the molecular programs. And notably, by the end of the year, we received FDA clearance for AmpliVue® C. difficile, the world's first handheld, disposable device for the amplification and detection of what has become a highly prevalent hospital-acquired pathogen.

Sofia

Our strategy for Sofia has been straightforward and simple, and has now been validated by our early success. We hypothesized that customers would prefer rapid point-of-care assays that could be objectively interpreted by an instrument, and therefore, were easier to use. Further, we thought that the physicians who order Influenza tests would appreciate the noticeable improvement in their ability to identify positive patients. We now know that these two key attributes of Sofia were the driving factors in our customers' decisions to acquire a Sofia analyzer, which bodes well for us as we anticipate the imminent introduction of other Sofia tests. In the near-term, we expect to introduce other respiratory assays and a qualitative pregnancy test, with the intent of solidifying and potentially expanding our existing served market. Beyond that, we intend to deliver products that address the women's health segment, several of which are quantitative assays, with market sizes that are much larger than our historical potential available market.

AmpliVue

With AmpliVue, we have combined two well understood technologies, isothermal amplification of genetic material and lateral flow immunoassay detection, to produce an easy-to-use, lower cost platform that delivers much improved accuracy over traditional laboratory methods for the detection of a number of infectious diseases. Our first AmpliVue assay for C. difficile requires neither an upfront extraction step that can create additional costs for the hospital lab, nor expensive thermocycling equipment that may prohibit many lower-volume hospitals from adopting on-site molecular testing capability, further delaying their conversion to the testing methodology that is considered to be state-of-the-art for the detection of hospital-acquired infections. The *C. difficile* product, which was cleared by the FDA in December and has since received a moderate complexity designation, is currently being sold in the U.S., as well as internationally. Other tests in development include Pertussis/Parapertussis, Group B Streptococcus, Herpes Simplex Viruses 1 and 2, *Trichomonas vaginalis*, and MRSA.

A Molecular Future

In addition to our handheld molecular platform, AmpliVue, we have developed and continue to develop Quidel Molecular real-time PCR assays for two strategic purposes. For the immediately addressable market, we are developing a series of PCR-based molecular assays that offer many workflow and storage advantages. These products are specifically designed to be run on FDA-cleared thermocyclers under identical thermocycling conditions for customers in high complexity, higher throughput settings. Trends that seem to be emerging for these high complexity customers are twofold: many are considering whether to replace their laboratory developed tests with FDA-cleared tests manufactured under GMP regulations; and, multiplexed panels used in the diagnosis of respiratory and gastrointestinal illness are being ordered more frequently by a growing number of physicians. In the near-term, the format and performance of the Quidel Molecular real-time PCR assays addresses both these trends nicely. There is a longer term strategic purpose, however, as these same assays are designed to be portable to our fully integrated molecular diagnostic platform, Savanna,™ with the expectation that upon launch of the platform in the developed world in the not too distant future, the instrument would be introduced with the menu necessary for success in the medium volume molecular diagnostic segment.

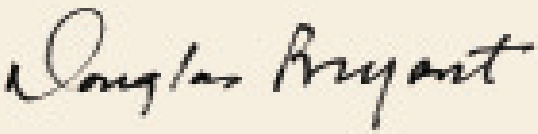
For the immediately addressable market, we are developing a series of PCR-based molecular assays that offer many workflow and storage advantages.

"We received FDA clearance for AmpliVue C. difficile, the world's first handheld, disposable device for the amplification and detection of what has become a highly prevalent hospital-acquired pathogen."

The Savanna instrument development program, itself, remains on track. In the fourth quarter, we were awarded a milestone-based grant from the Bill and Melinda Gates Foundation to further develop, manufacture, and validate a quantitative, low-cost nucleic acid assay for HIV drug treatment monitoring. Savanna uses our novel, proprietary Phase Gate™ extraction technology to dramatically reduce the time, complexity, and cost associated with sample preparation and purification. This novel technology is the basis for our belief that we will meet cartridge cost targets that are necessary for markets, like Africa, and other limited resource settings. Equally important, we believe that our simple cartridge design and lower cost will give us a competitive advantage that will also serve us well in markets like the U.S.

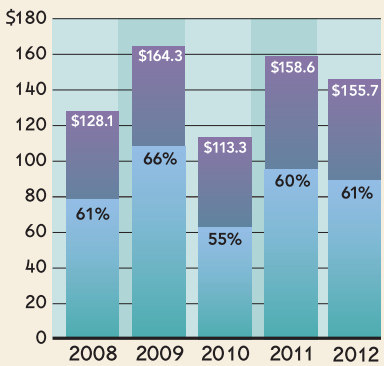
As a fellow shareholder, I am pleased to see Quidel's pipeline of innovative, competitive products evolve, and am excited as key milestones are achieved. As the leader of this high performing team, I am especially proud of what we have accomplished in a relatively short period of time, and of the culture that now pervades our company. On behalf of the 500 plus employees of Quidel, thank you for your continued confidence and support.

Sincerely,

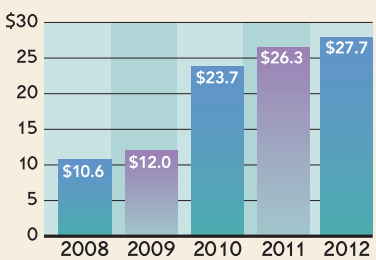


Douglas Bryant

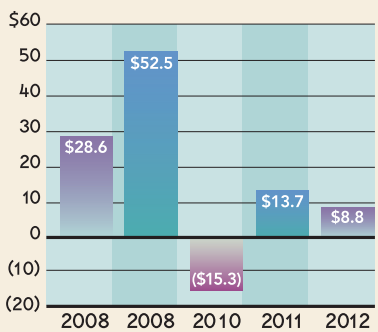
President and CEO
Quidel Corporation
March 2013



Annual Revenue
(in millions, percent gross margin in black)



Annual R&D Investment
(in millions)



Annual Operating Income
(in millions)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2012

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from N/A to N/A

Commission file number: 0-10961

QUIDEL CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE	**94-2573850**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
10165 McKellar Court **San Diego, California** (Address of principal executive offices)	**92121** (Zip Code)

858-552-1100

(Registrant's telephone number, including area code)

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☒	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $441,723,475 based on the closing sale price at which the common stock was last sold, as of the last business day of the registrant's most recently completed second fiscal quarter.

As of February 14, 2013, 33,489,582 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

(To the Extent Indicated Herein)

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the registrant's 2013 Annual Meeting of Stockholders (to be held on May 14, 2013) are incorporated by reference into Part III, Items 10, 11, 12, 13 and 14 of this Annual Report on Form 10-K.

A Warning About Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, seasonality; the timing of onset, length and severity of cold and flu seasons; the level of success in executing on our strategic initiatives; our reliance on sales of our influenza diagnostic tests; uncertainty surrounding the detection of novel influenza viruses involving human specimens; our ability to develop new products and technology; adverse changes in the competitive and economic conditions in domestic and international markets; our reliance on and actions of our major distributors; technological changes and uncertainty with research and technology development, including any future molecular-based technology; the medical reimbursement system currently in place and future changes to that system; manufacturing and production delays or difficulties; adverse regulatory actions or delays in product reviews by the U.S. Food and Drug Administration (the "FDA"); compliance with FDA and environmental regulations; our ability to meet unexpected increases in demand for our products; our ability to execute our growth strategy, including the integration of new companies or technologies; disruptions in the global capital and credit markets; our ability to hire key personnel; intellectual property, product liability, environmental or other litigation; potential required patent license fee payments not currently reflected in our costs; adverse changes in our international markets, potential inadequacy of booked reserves and possible impairment of goodwill; and lower than anticipated acceptance, sales or market penetration of our new products. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," and similar words, although some forward-looking statements are expressed differently. Forward-looking statements in this Annual Report include, among others, statements concerning: our outlook for the upcoming fiscal year, including projections about our revenue, gross margins, expenses, and the effective tax rate; projected capital expenditures for the upcoming fiscal year and our source of funds for such expenditures; the sufficiency of our liquidity and capital resources; the future impact of deferred tax assets or liabilities; the expected vesting periods of unrecognized compensation expense; and our intention to continue to evaluate technology and Company acquisition opportunities. The risks described under "Risk Factors" in Item 1A of this Annual Report and elsewhere herein and in reports and registration statements that we file with the Securities and Exchange Commission (the "SEC") from time to time, should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report. The following should be read in conjunction with the audited Consolidated Financial Statements and Notes thereto beginning on page F-1 of this Annual Report. We undertake no obligation to publicly release the results of any revision or update of these forward-looking statements, except as required by law.

Part I

Item 1. Business

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

Overview

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

We are a corporation, incorporated in the State of Delaware. Our executive offices are located at 10165 McKellar Court, San Diego, California 92121, and our telephone number is (858) 552-1100. This Annual Report and each of our other periodic and current reports, including any amendments thereto, are available, free of charge, on our website, *www.quidel.com*, as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The information contained on our website is not incorporated by reference into this Annual Report and should not be considered part of this Annual Report. In addition, the SEC website contains reports, proxy and information statements, and other information about us at *www.sec.gov*.

Business Strategy

Our primary objective is to build a broader-based diagnostic company, with products in market segments that are growing, and in which we have significant expertise and know-how, and, in doing so, to realize increased shareholder value.

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

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

Our strategy to accomplish our primary objective includes the following:

- leveraging our current infrastructure to develop and launch new lateral flow and DFA products such as additional assays for our FDA approved Sofia™ Analyzer;
- developing a molecular diagnostics franchise that incorporates two distinct testing platforms, AmpliVue™ and Savanna™; 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 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;
- strengthening 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

- 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 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 or hospital unit to a central laboratory. In a typical visit to the physician's office, after the patient's test specimen is collected, the patient is usually sent home and receives the results of the test several hours or days later. The result of this process is that the patient may leave the physician's office without confirmation of the diagnosis and the opportunity to begin potentially more effective immediate care.

Decentralized POC market

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

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

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

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

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

Products

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

Infectious Diseases

QuickVue® *Influenza.* 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. Our first QuickVue® influenza test received FDA clearance in September 1999, with commercialization beginning in December 1999. The FDA granted us the

first CLIA waiver for an influenza test in October 2000. Our second generation test, the QuickVue® Influenza A+B test, which allows for the differential diagnosis of influenza type A and type B, received FDA clearance in September 2003 and a CLIA waiver in February 2004.

Group A Strep. 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. The tests are used to aid in the diagnosis of Group A Streptococcal infection. Each year millions of people in the U.S. are tested for Group A Strep infections, commonly referred to as "strep throat." Group A Streptococci are bacteria that typically cause illnesses such as tonsillitis and pharyngitis which, if left untreated, can progress to secondary complications. Our initial Strep A test, the QuickVue In-line® Strep A test, was the first rapid Strep A test to be granted a CLIA waiver, and we launched additional product offerings with the QuickVue®+ Strep A and the QuickVue® Dipstick Strep A tests in 1996 and 2001, respectively.

RSV Test. Our QuickVue® RSV test is a rapid immunoassay for Respiratory Syncitial Virus ("RSV"). 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. We launched our RSV test during the fourth quarter of 2006, and we received CLIA waiver in February 2008. In September 2010, we received 510(k) clearance for the sale of our QuickVue® RSV 10 test. QuickVue® RSV 10 detects the RSV antigen directly from nasopharyngeal swab and nasopharyngeal aspirate/wash specimens from symptomatic patients under the age of six. QuickVue® RSV 10 employs the identical test method and sample preparation of our QuickVue® Influenza A+B test, allowing for the use of the same nasopharyngeal patient specimen when testing for influenza or an RSV infection.

Multiplex Respiratory. Our cell culture and DFA detection solutions are used by reference laboratories, public health labs and acute care hospitals to detect seven major viral respiratory pathogens. Our proprietary cell culture platform R-Mix™ combined with our FDA cleared antibody kit D³® Ultra™ DFA, detects Influenza A and B, RSV, Adenovirus and Parainfluenza types 1, 2 and 3, with turn-around times between 16 and 48 hours. The same D³® Ultra DFA™ antibody kit can also be used for direct specimen testing for those viruses with turn-around times in less than 90 minutes. In 2009, we introduced a new FDA cleared technology called D³® FastPoint™ that detects eight viruses, with Human Metapnuemo Virus added to the testing menu. D³® FastPoint™ provides laboratories, in a direct specimen testing format, the ability to produce virus identification in less than 25 minutes from specimen receipt.

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

Herpes and Herpes Family. Our proprietary engineered cell culture system, ELVIS® HSV, is an FDA cleared and highly sensitive system for the isolation and detection of Herpes Simplex Virus ("HSV") types 1 and 2. Herpes is a widespread sexually transmitted infection with an HSV 2 prevalence rate of 16% of the population according to the Centers for Disease Control ("CDC"). We also provide a multiplex cell culture solution using a propriety cell platform called H&V-Mix ™ that is used to isolate HSV, Varicella Zoster Virus 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.

Sofia™ Analyzer. Sofia™ is the brand name for our update to include our next generation fluorescent immunoassay ("FIA") system. The easy-to-use Sofia™ Analyzer, Sofia™ Influenza A+B FIA test, and Sofia™ Strep A FIA test combine unique software and fluorescent chemistry 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 ("LIS") to hospital and medical center databases. The Sofia™ FIA test employs advanced lateral flow and immunofluorescence technologies to provide enhanced performance for Influenza A and B, Strep A, RSV, and Legionella. 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. These features help ensure a reliable, objective, rapid and accurate diagnostic result.

- In late 2011, we received 510(k) clearance from the FDA and the European Conformity Mark ("CE Mark") in Europe for the sale of the Sofia™ Analyzer and the Sofia™ Influenza A+B FIA.

- Also in 2011, we also received the CE Mark in Europe for the Sofia™ Strep A FIA test.

- In 2012, we received the CE Mark in Europe for the Sofia™ Legionella FIA test and the Sofia™ RSV FIA test.

- Also in 2012, we received CLIA Waiver for our Sofia™ Analyzer and the Sofia™ Influenza A+B FIA test.

Molecular Open Box. These assays run on the Applied Biosystems® 7500 Fast DX thermocycler or the Cepheid SmartCycler® thermocycler. They are the first of several planned Quidel® Molecular Real-Time PCR Assays that provide important benefits to the customer, including, among others, room temperature storage, reduced process time, and ready-to-use reagent configurations.

- In 2011, we received 510(k) clearance and the CE Mark for the sale of the Quidel® Molecular Influenza A+B Real-Time RT-PCR Assay and the Quidel® Molecular Human Metapneumovirus ("hMPV") Assay.

- In 2012, we received CE Mark for our Molecular Diagnostic Test for RSV and hMPV.

- In 2012, we received 510(k) clearance for our Quidel Molecular ™ Influenze A+B assay.

- Also in 2012, we received CE Mark for our Direct Specimen Rapid PCR Test for Toxigenic Clostridium Difficile.

Molecular Amplivue® Hand-Held Molecular Diagnostic. For this assay, the detection of the pathogen is achieved using a hand-held, fully contained cassette that combines isothermal Helicase Dependent Amplification (HDA) with its lateral flow detection technology.

- In 2012, we received 510(k) clearance and the CE Mark for Amplivue® Hand-Held Molecular Diagnostic Test for Clostridium Difficile.

POC Women's Health

Pregnancy. Our QuickVue® pregnancy tests are used in both physicians' office labs and acute care settings. In August 2010, we received 510(k) clearance for the sale of our RapidVue® hCG test which is a lateral flow pregnancy test. 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. Our QuickVue® and RapidVue®pregnancy tests are sensitive immunoassay tests for the qualitative detection of human Chorionic Gonoadotropin ("hCG") in serum or urine for the early detection of pregnancy.

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. Enteroviruses such as Coxsackievirus A16 are referred to as Hand Foot and Mouth disease and commonly affect infants and children. Our indirect fluorescent antibody (IFA) products sold under the name Super E-Mix™ and D³ IFA Enterovirus kit are used by reference laboratories and acute care hospitals.

Helicobacter pylori ("H. pylori"). H. pylori is the bacterium associated with approximately 80% of patients diagnosed with peptic ulcers in the U.S. *H. pylori* is implicated in chronic gastritis and is recognized by the World Health Organization as a Class 1 carcinogen that may increase a person's risk of developing stomach cancer. Once an *H. pylori* infection is detected, antibiotic therapy is administered to eradicate the organism and effect a cure of the ulcer. Our rapid test is a serological test that measures antibodies circulating in the blood caused by the immune response to the *H. pylori* bacterium. Our initial test was the first rapid *H. pylori* test to be granted a CLIA waiver. We launched our second-generation CLIA-waived test, the QuickVue® H. Pylori gII™ test, in August 2000.

Our Specialty Products Group ("SPG") located in Santa Clara, California 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. The SPG revenues, income and assets are less than 10% of our overall operations.

Seasonality

Sales of our infectious disease products are subject to, and significantly affected by, the seasonal demands of the cold and flu seasons, prevalent during the fall and winter. As a result of these seasonal demands, we typically experience lower sales volume in the second and third quarters of the calendar year, and have higher sales in the first and fourth quarters of the calendar year. Historically, sales of our infectious disease products have varied from year to year based in large part on the severity, length and timing of the onset of the cold and flu season. For the years ended December 31, 2012, 2011 and 2010, sales of our infectious disease products accounted for 71%, 71% and 61%, respectively, of total revenue.

Research and Development

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

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

Research and development expenses were approximately $27.7 million, $26.3 million and $23.7 million for the years ended December 31, 2012, 2011 and 2010, respectively. We anticipate that we will continue to devote a significant amount of financial resources to product and technology research and development for the foreseeable future.

Marketing and Distribution

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

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

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

The sales, distribution and service of our highly complex diagnostic tests are controlled exclusively by us. Since the acquisition of DHI and the integration of the hospital sales forces of the two companies, laboratory end-users in hospitals and clinical reference laboratories utilizing our highly complex diagnostic tests are reached through our own direct sales force and technical support services that have specialized training and understanding of the product portfolio.

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

During 2012, we continued to invest in several key areas: support for clinical research and expanding our communications through promotional campaigns, peer-reviewed technical publications, professional shows and exhibits, symposia, medical education and support of health economics and outcomes research.

We derive a significant portion of our total revenue from a relatively small number of distributors. Four of our distributors, which are considered to be among the market leaders, collectively accounted for approximately 42%, 40% and 31% of our total revenue for the years ended December 31, 2012, 2011 and 2010, respectively. We had sales to two distributors for whom sales exceeded 10% of total revenue for the year ended December 31, 2012. The distributors were Cardinal Healthcare Corporation and McKesson Corporation.

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

Manufacturing

In 2012, we had manufacturing operations in San Diego and Santa Clara, California and Athens, Ohio. The San Diego facility produces our lateral flow, immunoassay products. The Santa Clara facility manufactures our microtiter plate products and our molecular products. The Athens facility manufactures our cell cultures and monoclonal antibody kits.

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

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

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

Government Regulation

Regulation in the United States

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

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

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

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

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

Regulation Outside of the United States

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

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

Intellectual Property

The healthcare industry has traditionally placed considerable importance on obtaining and maintaining patent and trade secret protection for commercially relevant technologies, devices, products and processes. We and other companies engaged in research and development of new diagnostic products actively pursue patents for technologies that are considered novel and patentable. However, important factors, many of which are not within our control, can affect whether and to what extent patent protection in the U.S. and in other important markets worldwide is obtained. By way of example, the speed, accuracy and consistency in application of the law in a patent office within any particular jurisdiction is beyond our control and can be unpredictable. The resolution of issues such as these and their effect upon our long-term success is likewise indeterminable. We have issued patents, both in the U.S. and internationally, with expiration dates ranging from the present through approximately 2029 and have patent applications pending throughout the world.

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

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

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

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

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

Competition

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

Many of our current and prospective commercial competitors, including several large pharmaceutical and diversified healthcare companies, have substantially greater financial, marketing and other resources than we have. These competitors include, among others, Alere Inc. (“Alere”), Beckman Coulter Primary Care Diagnostics (“Beckman”), Fisher Scientific Corporation (“Fisher”), Becton Dickinson and Company (“Becton”), Meridian Bioscience, Inc. (“Meridian”) and Chemicon

International, Inc. ("Chemicon"). We also face competition from our distributors since some have created, and others may decide to create, their own products to compete with ours. Competition may also be provided from large, medium and small development companies whose portfolio and technologies are dedicated to the development of diagnostic solutions in areas of infectious diseases in which we currently have relevant market share.

Human Resources

As of December 31, 2012, we had 514 employees, none of whom are represented by a labor union. We have experienced no work stoppages and believe that our employee relations are good.

Executive Officers of Quidel Corporation

The names, ages and positions of all executive officers as of December 31, 2012 are listed below, followed by a brief account of their business experience. There are no family relationships among these officers, nor any arrangements or understandings between any officer and any other person pursuant to which an officer was selected.

Douglas C. Bryant, 55, was named President, Chief Executive Officer and a member of the Board of Directors in February 2009. Mr. Bryant's appointment as President and Chief Executive Officer was effective on March 1, 2009. Prior to joining us, Mr. Bryant served as Executive Vice President and Chief Operating Officer at Luminex Corporation, managing its Bioscience Group, Luminex Molecular Diagnostics (Toronto), manufacturing, R&D, technical operations, and commercial operations. From 1983 to 2007, Mr. Bryant held various worldwide commercial operations positions with Abbott Laboratories including, among others: Vice President of Abbott Vascular for Asia/Japan, Vice President of Abbott Molecular Global Commercial Operations and Vice President of Abbott Diagnostics Global Commercial Operations. Earlier in his career with Abbott, Mr. Bryant was Vice President of Diagnostic Operations in Europe, the Middle East and Africa, and Vice President of Diagnostic Operations Asia Pacific. Mr. Bryant has over 25 years of industry experience in sales and marketing, product development, manufacturing and service and support in both the diagnostics and life sciences markets. Mr. Bryant holds a B.A. in Economics from the University of California at Davis.

Randall J. Steward, 58, became our Chief Financial Officer on October 31, 2011. Prior to joining us, Mr. Steward served as the Chief Financial Officer for Navilyst Medical, Inc, a medical device company based in Massachusetts. From 2008 to January 2011, Mr. Steward served as Chief Operating Officer for SeQual Technologies, Inc., a San Diego-based medical device company, where he was responsible for all aspects of engineering, manufacturing, finance, and information systems. Prior to SeQual Technologies, Mr. Steward spent 11 years with Spectrum Brands as Executive Vice President and Chief Financial Officer. Mr. Steward holds a B.B.A. in Accounting from Southern Methodist University. He is also a Certified Public Accountant and a member of the American Institute of Certified Public Accountants.

Timothy T. Stenzel, M.D., Ph.D., 51, became our Chief Scientific Officer in September 2009. Prior to joining us, Dr. Stenzel was Vice President and Chief Medical Officer since 2007 for Asuragen Inc (Austin, TX). Dr. Stenzel has also held senior positions at Abbott Laboratories from 2003 to 2007 and Duke University from 1997 to 2003, where he established Duke's molecular laboratory capabilities. Dr. Stenzel received his M.D. and Ph.D. from Duke University and a B.A. in Chemistry from Grinnell College.

Robert J. Bujarski, J.D., 44, became our Senior Vice President, General Counsel and Corporate Secretary in June 2008 and in 2010 became our Senior Vice President, Business Development, General Counsel and Corporate Secretary. Mr. Bujarski previously served as our Senior Vice President, General Counsel and Corporate Secretary from March 2007 through March 2008. From July 2005 to March 2007, he was our General Counsel and Vice President. Mr. Bujarski was an associate attorney with the law firm of Gibson, Dunn & Crutcher LLP in its transactions practice group from October 2001 to July 2005. Mr. Bujarski received his B.A. degree in 1991 and his law degree in 2001 from the University of Arizona.

Mark W. Smits, 55, has served as Senior Vice President of Commercial Operations since May 2011. From August 2010 to May 2011 Mr. Smits served as Vice President of Sales and Marketing for Neogenomics, a provider of cancer-focused testing laboratories. From October 2008 to August 2010, Mr. Smits was Vice President of Marketing and Business Development for Fisher HealthCare, Inc., a division of Thermo Fisher Scientific, Inc. which is a supplier of analytical instruments, laboratory equipment, software, services, consumables and reagents. Mr. Smits led the sourcing and business development efforts for Fisher HealthCare. Prior to Fisher HeatlthCare, Mr. Smits spent 25 years with Abbott Diagnostics, which offers instrument systems and tests for hospitals, reference labs, blood banks, physician offices, and clinics, serving in several different roles including, from October 2002 until September 2008, Divisional Vice President, Western United States Commercial Operations, where he led an organization of 250 people to provide sales, service and support to customers. Mr. Smits received his B.S. from Texas A&M University.

Scot M. McLeod, 48, has been our Senior Vice President, Operations since July 2007. Mr. McLeod previously served as the Company's Vice President, Operations from 2001 to July 2007. Mr. McLeod first joined the Company in 1997 as Director of Production and has held various management operations positions with the Company throughout his 14 years of service. Mr. McLeod has over 20 years experience in operations and a diverse manufacturing background in both domestic and international environments. Mr. McLeod spent five years with an overseas manufacturer of computer peripherals. Prior to joining Quidel, Mr. McLeod held various positions in operations and quality with Medtronic Interventional Vascular, Hybritech Inc., ALCOA and Information Magnetics Corporation. Mr. McLeod has his B.S. in Chemical Engineering from the University of New Hampshire.

John D. Tamerius, Ph.D., 67, has been our Senior Vice President, Clinical/Regulatory Affairs since November 2008. Dr. Tamerius previously served as the Company's Vice President, Clinical/Regulatory Affairs from 2005 to November 2008. Dr. Tamerius has held a variety of positions with us including, among others: Vice President for Research and Development and General Manager of the Company's Specialty Products Group. Dr. Tamerius joined the Company in 1983 with the acquisition of Cytotech, Inc. where he served as President. Dr. Tamerius was previously a research associate at Scripps Clinic and Research Foundation. Dr. Tamerius performed postdoctoral research in tumor immunology at the Fred Hutchinson Cancer Center in Seattle and was awarded a Bachelor of Science, Master of Science, and Doctor of Philosophy in Microbiology and Immunology, all from the University of Washington.

Item 1A. Risk Factors

Risks Related to Our Business

Our operating results may fluctuate adversely as a result of many factors that are outside our control.

Fluctuations in our operating results, for any reason, could cause our growth or operating results to fall below the expectations of investors and securities analysts. For the year ended December 31, 2012, total revenue decreased 2% to $155.7 million from $158.6 million for the year ended December 31, 2011. The decrease in total revenues was primarily due to a lack of a cold and flu season in the first quarter of 2012 partially offset by an early start to the 2012/2013 cold and flu season in the fourth quarter of 2012. For further discussion of this increase, refer to Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operation" included in this Annual Report.

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

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 larger and better financed competitors introduced a new 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 sales levels because a significant portion of our costs are fixed costs, relatively higher sales would be expected to increase profitability, while relatively lower sales would not reduce costs by the same proportion, and could cause operating losses;
- lower than anticipated market penetration of our new or more recently introduced products;
- significant quantities of our product or that of our competitors in our distributors' inventories or distribution channels;
- changes in distributor buying patterns; and
- changes in the health care market including consolidation in our customer base.

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

Our ability to compete successfully in the diagnostic market depends on continued development and introduction of new proprietary technology and the improvement of existing technology. If we cannot continue to develop, obtain and protect proprietary technology, our total revenue and gross profits could be adversely affected. Moreover, our current and future licenses may not be adequate for the operation of our business.

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 2029. Additionally, we have patent applications pending in 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. In addition to our patents in the U.S., we have patents issued in various other countries including, Australia, Canada, Japan and various European countries, including France, Germany, Italy, Spain and the United Kingdom. Third parties can make, use and sell products covered by our patents in any country in which we do not have patent protection. We also license the right to use our products to our customers under label licenses that are for research purposes only. These licenses could be contested and, because we cannot monitor all potential unauthorized uses of our products around the world, we might not be aware of an unauthorized use or might not be able to enforce the license restrictions in a cost-effective manner. 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. Also, we may not be able to obtain licenses for technology patented by others and required to produce our products on commercially reasonable terms.

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 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. Moreover, no assurances can be given that our efforts to develop new technologies or products will be successful or that such technologies and products will be commercially viable.

The development of new markets also requires a substantial investment of resources, such as new employees, offices and manufacturing facilities. Accordingly, we are likely 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 growth strategies discussed in Item 1 of this Annual Report.

As a result of any number of risk factors identified in this Annual Report, no assurance can be given that we will be successful in implementing our operational, growth and other strategic efforts. In addition, the funds for our strategic development projects have in the past come primarily from our business operations and 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 will have to decide at that time which programs to reduce or eliminate, and by how much. Similarly, if adequate financial, personnel, equipment or other resources are not available, we may be required to delay or scale back our strategic efforts. Our operations will be adversely affected if our total revenue and gross profits do not correspondingly increase 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 which 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 42%, 40% and 31% of our total revenue for the years ended December 31, 2012, 2011 and 2010, respectively. We had sales to two distributors for whom sales exceeded 10% of total revenue for the year ended December 31, 2012. 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 to 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, 2012, 2011 and 2010, sales of our infectious disease products (including influenza test sales) accounted for 71%, 71% and 61%, respectively, of total revenue.

If we are not able to manage our growth strategy or if we experience difficulties integrating companies or technologies we may acquire after their acquisition, our earnings 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. We may experience difficulties integrating the operations of other companies or technologies that we may acquire with our own operations, and as a result we may not realize our anticipated benefits and cost savings within our expected time frame, or at all. Because we have a relatively small executive staff, future growth may also divert management's attention from other aspects of our business, and will 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. 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 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. Acquisitions may subject us to other risks, including unanticipated costs and expenditures, 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. 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 of revenue and expose us to significant liability.

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

- pending litigation may of itself cause our distributors or end-users to reduce or terminate purchases of our products;
- it may consume a substantial portion of our managerial and financial resources;
- its outcome would be uncertain and a court may find any third-party patent claims valid and infringed by our products (issuing a preliminary or permanent injunction) that would require us to 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 $9.4 million, $10.9 million and $7.8 million for the years ended December 31, 2012, 2011 and 2010, 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 Senior Credit Facility amends and restates our $120.0 million senior secured credit facility dated October 8, 2008. As part of this amendment, we incurred $1.0 million in deferred financing costs related to the Senior Credit Facility in addition to the $0.6 million we had previously recorded related to the original credit facility. As of December 31, 2012, we had $1.5 million included as a portion of other non-current assets. The Senior Credit Facility bears interest at either on the London Interbank Offered Rate ("LIBOR") or the base rate plus in each case the applicable margin. The base rate is equal to the highest of (i) the lender's prime rate, (ii) the federal funds rate plus one-half of one percent and (iii) LIBOR plus one percent. The applicable margin is generally determined in accordance with a performance pricing grid based on our leverage ratio and ranges from 1.25% to 2.50% for LIBOR rate loans and from 0.25% to 1.50% for base rate loans (weighted average interest rate of 1.46% at December 31, 2012). The agreement governing the Senior Credit Facility is subject to certain customary limitations, including among others: limitation on liens; limitation on mergers, consolidations and sales of assets; limitation on debt; limitation on dividends, stock redemptions and the redemption and/or prepayment of other debt; limitation on investments (including loans and advances) and acquisitions; limitation on transactions with affiliates; and limitation on disposition of assets. We are also subject to financial covenants which include a funded debt to adjusted earnings before interest, taxes, depreciation and amortization, and stock-based compensation ("adjusted EBITDA") ratio (as defined in the Senior Credit Facility) not to exceed 3:1 as of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:1 as of the end of each fiscal quarter. The Senior Credit Facility is secured by substantially all of our present and future assets and properties. If we fail to comply with these covenants, our Senior Credit Facility could become due and payable prior to maturity. As of December 31, 2012 we were in compliance with all financial covenants.

We may incur significant additional indebtedness. Our indebtedness could be costly or have adverse consequences.

We may incur significant additional indebtedness, subject to the restrictions in our Senior Credit Facility. As of December 31, 2012, we had $110.4 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 of December 31, 2012, we had $5.0 million outstanding under the Senior Credit Facility. Our borrowing capacity can fluctuate from time to time due to, among other factors, our funded debt to adjusted EBITDA ratio as and when measured under the Senior Credit Facility.

Our indebtedness could be costly or have adverse consequences, such as:

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

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 the financial covenants in the documents governing our indebtedness. As a result, we may need to seek to raise funds through public or private debt or sale of equity to achieve our business strategy 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. These conditions could adversely affect the demand for our products and services and, therefore, reduce purchases by our customers, which would negatively affect our revenue growth and cause a decrease in our profitability. 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 earnings and cash flow. 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. If economic conditions remain volatile, our results of operations or financial condition could be adversely affected.

We may not achieve market acceptance of our products among physicians and other healthcare providers, 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 in our budget, our total revenue will not grow as much as we expect and the costs we incur or have incurred will be disproportionate to our sales levels. We expect that clinical reference and hospital-based laboratories will continue to compete vigorously against our POC diagnostic products in order to maintain and expand their existing dominance of the overall diagnostic testing market. Moreover, even if we can demonstrate that our products are more cost-effective, save time, or have better performance, physicians and other healthcare providers may resist changing to POC tests. Our failure to achieve market acceptance from physicians and healthcare providers with respect to the use of our POC diagnostic products would have a negative effect on our future sales growth.

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

In addition to competition from laboratories, our POC 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. 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 and cannot predict with certainty how industry consolidation will affect our competitors or us. 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. 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 total revenue and profits could be materially and adversely affected.

Our products are highly regulated by various governmental agencies. Any changes to the existing laws and regulations may 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, when and at what cost we will receive regulatory approval for new products. 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. Regulatory review can be a lengthy, expensive and uncertain process, making the timing and costs of clearances and approvals difficult to predict. Our total revenue would be negatively affected by failures or delays in the receipt of approvals or clearances, the loss of previously received approvals or clearances or the placement of limits on the marketing and use of our products.

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 recently adopted healthcare reform bill signed into law 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. 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, 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 and results of operations could be adversely affected.

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

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

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

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

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

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

Our inability to meet customer demand for our products, whether as a result of manufacturing problems or supply shortfalls, could harm our customer relationships and impair our reputation within the industry. 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 total revenue and profitability.

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

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

Some of our raw materials and components are currently obtained from a sole supplier or a limited group of suppliers. We have long-term supply agreements with many of these suppliers, but these long-term agreements involve risks for us, such as our potential inability to obtain an adequate supply of quality raw materials and components and our reduced control over pricing, quality and timely delivery. It is also possible that one or more of these suppliers may become unwilling or unable to deliver materials or components to us. 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 total revenue or cost of sales and related profits.

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 profitability 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.

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.

Our products are sold internationally, with the majority of our international sales to our customers in Japan and Europe. We currently sell and market our products through distributor organizations and sales agents. Sales to foreign customers accounted for 14%, 14%, and 15% of our total revenue for the years ended December 31, 2012, 2011 and 2010, 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 the Foreign Corrupt Practices Act and local laws prohibiting corrupt payments to governmental officials, could expose us or our employees to fines and criminal sanctions and damage our reputation;
- tariffs or other barriers as we continue to expand into new countries and geographic regions;
- exposure to currency exchange fluctuations against the U.S. dollar;
- longer payment cycles, generally lower average selling prices and greater difficulty in accounts receivable collection;
- reduced, or lack of, protection for, and enforcement of, intellectual property rights;
- political and economic instability in some of the regions where we currently sell our products or that we may expand into in the future;
- potentially adverse tax consequences; and
- diversion to the U.S. of our products sold into international markets at lower prices.

Currently, the majority of our international sales are negotiated for and paid in U.S. dollars. Nonetheless, these sales are subject to currency risks, since changes in the values of foreign currencies relative to the value of the U.S. dollar can

render our products comparatively more expensive. These exchange rate fluctuations could negatively impact international sales of our products, as could changes in the general economic conditions in those markets. In order to maintain a competitive price for our products internationally, we may have to continue to provide discounts or otherwise effectively reduce our prices, resulting in a lower margin on products sold internationally. Continued change in the values of the Euro, the Japanese Yen and other foreign currencies could have a negative impact on our business, financial condition and results of operations. In addition, we have a supply agreement with a foreign vendor whereby we evenly share the foreign currency exchange fluctuation risk. We may, in the future, enter into similar arrangements.

Investor confidence and our share price may be adversely impacted if we or our independent registered public accounting firm conclude that our internal controls over financial reporting are not effective.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring us, as a public company, to include a report of management on our internal controls over financial reporting in our Annual Reports on Form 10-K that contains an assessment by management of the effectiveness of our internal controls over financial reporting. In addition, our independent registered public accounting firm must attest to the effectiveness of our internal controls over financial reporting. The requirements of Section 404 of the Sarbanes-Oxley Act of 2002 are ongoing. We expect that our internal controls will continue to evolve as our business activities change. Although we seek to diligently and vigorously review our internal controls over financial reporting in an effort to ensure compliance with the Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. In addition, the integration of the business and operations of any future acquisitions could heighten the risk of deficiencies in our internal controls, particularly in the case of acquisitions of private companies, which may not have internal controls over financial reporting adequate for public company reporting. If, during any year, our independent registered public accounting firm is not satisfied with our internal controls over financial reporting or the level at which these controls are documented, designed, operated, tested or assessed, or if the independent registered public accounting firm interprets the requirements, rules or regulations differently than we do, then it may issue a report that is qualified. This could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements and effectiveness of our internal controls, which ultimately could negatively impact the market price of our shares.

Risks Related to Our Common Shares

Our stock price has been highly volatile, and an investment in our stock could suffer a significant decline in value.

The market price of our common shares has been highly volatile and has fluctuated substantially in the past. For example, between December 31, 2010 and December 31, 2012, the closing price of our common shares, as reported by the Nasdaq Global Market, has ranged from a low of $11.40 to a high of $18.96. We expect our common shares to continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including the risk factors discussed herein.

In addition, the stock market in general, and the Nasdaq Global 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. 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.

Future sales or other dilution of our equity could depress the market price of our common shares.

Sales of our common shares in the public market, or the perception that such sales could occur, could negatively impact the market price of our common shares. As of December 31, 2012:

- approximately 33.5 million of our common shares were issued, most of which are generally tradable in the public markets without restrictions;
- approximately 3.6 million of our common shares were issuable upon exercise of outstanding stock options under our various equity incentive plans at a weighted average exercise price of $13.50; and
- we had approximately 0.3 million of our common shares underlying restricted stock units.

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

In addition, the issuance of additional common shares, or issuances of securities convertible into or exercisable for our common shares or other equity linked securities, including, convertible debt, preferred stock or warrants, could dilute the ownership interest of our common stockholders and could depress the market price of our common shares and impair our ability to raise capital through the sale of additional equity securities.

We may need to seek additional capital. If this additional financing is obtained through the issuance of equity securities, debt convertible into equity or options or warrants to acquire equity securities, our existing stockholders could experience significant dilution upon the issuance, conversion or exercise of such securities.

Our governing documents and rights plan may delay stockholder actions with respect to business combinations or the election of directors, or delay or prevent a sale of the company or changes in management.

Our governing documents and our stockholder rights plan may have the effect of delaying stockholder actions with respect to business combinations or the election of directors, or delaying or preventing a sale of the company or a change in our management, including the following:

- Our amended and restated bylaws require stockholders to give written notice of any proposal or director nomination to us within a specified period of time prior to any stockholder meeting and do not permit stockholders to call a special meeting of the stockholders, unless such stockholders hold at least 50% of our stock entitled to vote at the meeting.
- Our Board of Directors may approve the issuance, without further action by the stockholders, of our preferred shares, and fix the rights and preferences thereof. An issuance of preferred shares with dividend and liquidation rights senior to our common shares or convertible into a large number of our common shares could prevent a potential acquirer from gaining effective economic or voting control.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our primary executive, administrative, manufacturing and research and development operation is located in San Diego, California where we lease a facility that is approximately 78,000 square feet. The San Diego lease expires in 2019 with options to extend the lease for three additional five-year periods. Also, we lease approximately 11,000 square feet of additional administrative office space in San Diego, and that lease expires in 2013 with an option to extend the lease for one additional two-year period. We lease approximately 24,000 square feet of manufacturing, laboratory and office space in Santa Clara, California. The Santa Clara lease expires in 2014 with an option to extend for one additional five-year period. We lease approximately 73,000 square feet of manufacturing, administrative and research and development space in Athens, Ohio. The Athens, Ohio lease expires in 2017 with options to extend the lease for two additional five-year periods.

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

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

Part II

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

COMMON STOCK PRICE RANGE

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

Quarter Ended	Low	High
December 31, 2012	$16.43	$18.96
September 30, 2012	15.00	18.93
June 30, 2012	15.01	18.90
March 31, 2012	14.18	18.38
December 31, 2011	$15.13	$18.83
September 30, 2011	12.73	16.37
June 30, 2011	11.70	15.88
March 31, 2011	11.40	14.74

As of February 14, 2013, we had approximately 472 common stockholders of record. No cash dividends were declared for our common stock during the fiscal years ended in 2012 or 2011, and we do not anticipate paying any dividends in the foreseeable future. Our Senior Credit Facility contains restrictions on the payment of cash dividends. See Note 2 in the Notes to Consolidated Financial Statements included in this Annual Report.

Stock Repurchases

The table below sets forth information regarding repurchases of our common stock by us during the three months ended December 31, 2012.

Period	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Approximate dollar value of shares that may yet be purchased under the plans or programs(1)
October 1 – October 31, 2012	—	$—	—	$22,081,000
November 1 – November 30, 2012	—	—	—	22,081,000
December 1 – December 31, 2012	—	—	—	22,081,000
Total	—	$—	—	$22,081,000

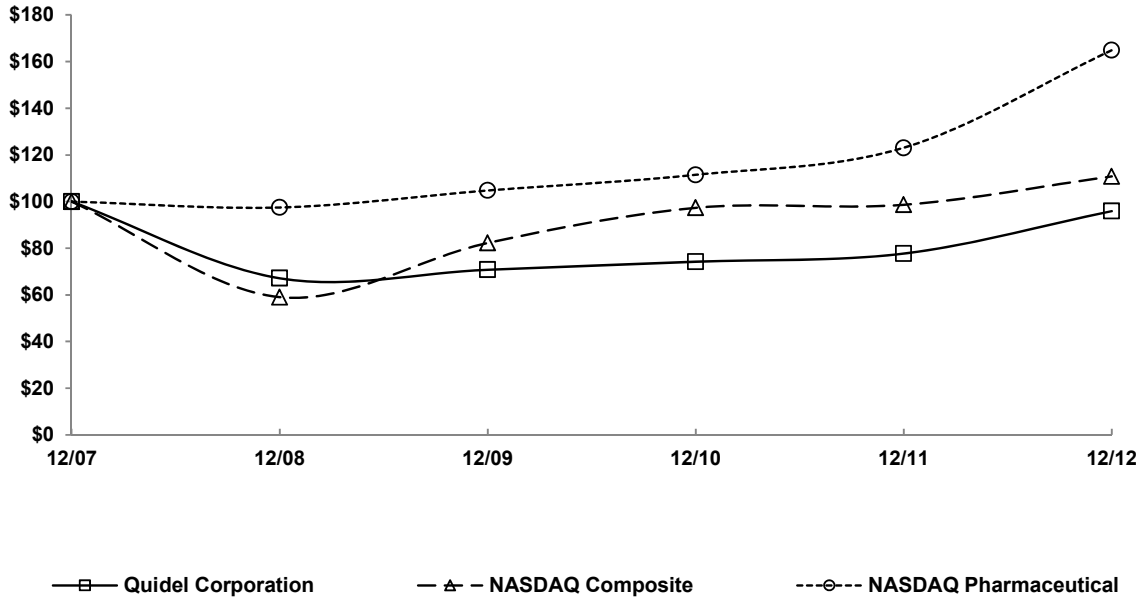
(1) On November 28, 2011, we announced that our Board of Directors authorized us to repurchase up to an aggregate of $25.0 million in shares of our common stock under our stock repurchase program. Any shares of common stock repurchased under this program will no longer be deemed outstanding upon repurchase and will be returned to the pool of authorized shares. This repurchase program will expire on November 8, 2013 unless extended by our Board of Directors.

STOCKHOLDER RETURN PERFORMANCE GRAPH

Set forth below is a line graph comparing the yearly percentage change in the cumulative total stockholder return on our common stock with the cumulative total return of the Nasdaq Composite Index and the Nasdaq Pharmaceutical Index for the period beginning December 31, 2007 and ending December 31, 2012. The graph assumes an initial investment of $100 on December 31, 2007 in our common stock, the Nasdaq Composite Index and the Nasdaq Pharmaceutical Index and reinvestment of dividends. The stock price performance of our common stock depicted in the graph represents past performance only and is not necessarily indicative of future performance.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Quidel Corporation, the NASDAQ Composite Index, and the NASDAQ Pharmaceutical Index



*$100 invested on 12/31/07 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

Company/Index	Base Period 12/31/07	12/31/08	12/31/09	12/31/10	12/31/11	12/31/12
Quidel Corporation	**$100.00**	$67.13	$70.78	$74.22	$77.71	$95.89
NASDAQ Composite	**100.00**	59.03	82.25	97.32	98.63	110.78
NASDAQ Pharmaceutical	**100.00**	97.45	104.75	111.47	123.06	164.89

Graph produced by Research Data Group, Inc. 1/10/2013

Item 6. Selected Financial Data

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

Consolidated Statements of Operations

	Year ended December 31,				
	2012	2011	2010(1)	2009	2008
	(in thousands, except per share data)				
Total revenues	$155,741	$158,603	$113,339	$164,282	$128,132
Costs and expenses					
Cost of sales (excludes amortization of intangible assets)(2)	61,285	62,865	51,489	55,218	50,206
Amortization of inventory fair value adjustment from acquisition	—	—	1,118	—	—
Total cost of sales (excludes amortization of intangible assets)(2)	61,285	62,865	52,607	55,218	50,206
Research and development	27,716	26,325	23,696	11,957	10,553
Sales and marketing	30,319	25,751	23,972	23,347	20,898
General and administrative	20,640	22,798	19,346	17,352	13,380
Amortization of intangible assets from acquired businesses and technology	6,935	7,124	6,731	1,364	4,476
Business acquisition and integration costs, and restructuring charges	—	—	2,276	2,495	—
Total costs and expenses	146,895	144,863	128,628	111,733	99,513
Operating income (loss)	8,846	13,740	(15,289)	52,549	28,619
Other (expense) income					
Interest income	41	203	214	372	1,686
Interest expense	(1,246)	(2,083)	(2,345)	(767)	(671)
Other (expense) income	(30)	(376)	—	(5)	135
Total other (expense) income	(1,235)	(2,256)	(2,131)	(400)	1,150
Income (loss) before provision (benefit) for taxes	7,611	11,484	(17,420)	52,149	29,769
Provision (benefit) for income taxes	2,618	3,851	(6,149)	19,266	10,921
Net income (loss)	$4,993	$7,633	$(11,271)	$32,883	$18,848
Basic earnings (loss) per share (3)	0.15	0.23	(0.39)	1.09	0.59
Diluted earnings (loss) per share	0.15	0.23	(0.39)	1.08	0.58
Shares used in basic per share calculation	33,068	32,903	28,582	29,964	31,853
Shares used in diluted per share calculation	33,702	33,320	28,582	30,272	32,612

Balance Sheet Data

	December 31				
	2012	2011	2010	2009	2008
	(in thousands)				
Cash, cash equivalents and marketable securities	$14,856	$61,332	$6,788	$93,002	$57,908
Working capital	$51,611	$71,452	$40,250	$96,699	$85,592
Total assets	$242,099	$278,894	$214,593	$166,345	$142,808
Long-term debt and lease obligations	$10,567	$47,947	$79,774	$6,527	$6,137
Stockholders' equity	$199,780	$185,386	$112,521	$126,450	$119,236
Common shares outstanding	33,451	33,276	28,514	29,026	31,894

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

(2) Excludes amortization of intangible assets of $5,753, $6,667, $5,852, $1,152 and $4,041 for the years ended December 31, 2012, 2011, 2010, 2009 and 2008, respectively.

(3) For the year ended December 31, 2009, we changed reported earnings per share per the Consolidated Statements of Operations included in this Annual Report to calculate using the two-class method, and, consequently, basic earnings per share decreased by $0.01 to $1.09 per share.

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

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

Overview and Executive Summary

We have a leadership position in the development, manufacturing and marketing of 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 U.S. through a network of national and regional distributors, and a direct sales force. Internationally, we sell and market primarily in Japan and Europe through distributor arrangements.

A majority of our total revenues relate to three product families. For the years ended December 31, 2012, 2011 and 2010, we derived approximately 58%, 59% and 51%, respectively, of our total revenues from sales of our influenza, Group A Strep and pregnancy tests. Additionally, a significant portion of our total revenue is from a relatively small number of distributors. Approximately 42%, 40% and 31% of our total revenue for the years ended December 31, 2012, 2011 and 2010, respectively, were related to sales through our four largest distributors.

For the year ended December 31, 2012, total revenue decreased 2% to $155.7 million from $158.6 million for the year ended December 31, 2011. The decrease in total revenues was primarily due to a lack of a cold and flu season in the first quarter of 2012 partially offset by an early start to the 2012/2013 cold and flu season in the fourth quarter of 2012.

Our primary objective is to build a broader-based diagnostic company, with products in market segments that are growing, and in which we have significant expertise and know-how, and, in doing so, to realize increased shareholder value.

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

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

Our strategy to accomplish our primary objective includes the following:

- leveraging our current infrastructure to develop and launch new lateral flow and DFA products such as additional assays for our FDA approved Sofia™ Analyzer;
- developing a molecular diagnostics franchise that incorporates two distinct testing platforms, AmpliVue™ and Savanna™; 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 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;
- strengthening 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
- 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 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.

As a business in a highly regulated and competitive industry, we face many risks and challenges and we also have opportunities. You should refer to the discussion in Item 1A, "Risk Factors" in Part I of this Annual Report for further discussion of risks related to our business.

Outlook

We anticipate revenue growth over the next 12 months and a related positive impact on gross margin and earnings as a result of increased sales of our Sofia assays and molecular products. In addition, we expect a continued increase in our investment in research and development activities as we invest in our molecular platforms, as well as a continued build of our sales organization to meet the placement strategy of our SOFIA products as well as new molecular assays. We will continue our focus on prudently managing our business and delivering solid financial results, while at the same time striving to continue to introduce new products to the market and maintaining our emphasis on research and development investments for longer term growth. Finally, we will continue to evaluate opportunities to acquire new product lines and technologies, as well as, company acquisitions.

Results of Operations

Comparison of years ended December 31, 2012 and 2011

Total Revenues

The following table compares total revenues for the years ended December 31, 2012 and 2011 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2012	2011	$	%
Infectious disease net product sales	$110,982	$112,227	($1,245)	-1%
Women's health net product sales	32,653	32,715	(62)	0%
Gastrointestinal disease net product sales	6,328	6,920	(592)	-9%
Other net product sales	3,326	4,322	(996)	-23%
Royalty, license fees and grant revenue	2,452	2,419	33	1%
Total revenues	$155,741	$158,603	($2,862)	-2%

For the year ended December 31, 2012, total revenue decreased 2% to $155.7 million from $158.6 million for the year ended December 31, 2011. The decrease in total revenues was primarily due to a lack of a cold and flu season in the first quarter of 2012 partially offset by an early start to the 2012/2013 cold and flu season in the fourth quarter of 2012.

The revenue from our royalty, license fees and grant revenue category for all periods primarily relate to royalty payments earned on our patented technologies utilized by third parties and revenue from grants for research and commercialization activities.

Cost of Sales

Cost of sales decreased 2.5% to $61.3 million, or 39% of total revenues, for the year ended December 31, 2012 compared to $62.9 million, or 40% of total revenues, for the year ended December 31, 2011. The absolute dollar decrease in cost of sales is primarily related to the variable nature of direct costs (material and labor) associated with the 2% decrease in total revenues in 2012, the $0.7 million charge in 2011 related to the Alere Amendment as discussed in Note 6 in the Notes to Consolidated Financial Statements, and $0.6 million related to a disposal of inventory associated with a discontinued product in 2011. This decrease was partially offset by an increase in depreciation of leased SOFIA instruments of $0.4 million in 2012.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2012 and 2011 (in thousands, except percentages):

	For the year ended December 31,					
	2012		2011		Increase (decrease)	
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues	$	%
Research and development	$27,716	18%	$26,325	17%	$1,391	5%
Sales and marketing	30,319	19%	25,751	16%	4,568	18%
General and administrative	20,640	13%	22,798	14%	(2,158)	-9%
Amortization of intangible assets from acquired businesses and technology	6,935	4%	7,124	4%	(189)	-3%

Research and Development Expense

Research and development expense for the year ended December 31, 2012 increased from $26.3 million to $27.7 million primarily due to increased activities related to the development of molecular and other potential new technologies.

These costs were partially offset by a research and development reimbursement of $3.0 million associated with a third-party collaboration agreement as more fully described in Note 1 in the notes to the Consolidated Financial Statements included in this annual report.

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

Due to the risks inherent in the product development process and given the early-stage of development of certain projects, we are unable to estimate with meaningful certainty the costs we will incur in the continued development of our product candidates for commercialization and, we have not historically tracked research and development costs by individual project. However, we expect our research and development costs to be substantial as we move other product candidates into preclinical and clinical trials and advance our existing product candidates into later stages of development.

Sales and Marketing Expense

Sales and marketing expense for the year ended December 31, 2012 increased from $25.8 million to $30.3 million primarily due to additional investments of $4.7 million in our sales organization including an increase in personnel, travel, training costs, and incentives related to new products. Other key components of this expense relate to continued investment in assessing future product extensions and enhancements and market research.

General and Administrative Expense

General and administrative expense for the year ended December 31, 2012 decreased from $22.8 million to $20.6 million partially due to a reduction in a liability of $0.5 million related to a technology license. In addition, 2011 stock-based compensation exceeded 2012 expense by $1.0 million primarily due to vesting of restricted stock awards. We expect general and administrative expenses to increase in 2013 as a result of the 2.3% medical device excise tax.

Amortization of Intangible Assets from Acquired Businesses and Technology

Amortization of intangible assets from acquired businesses consists of customer relationships, purchased technology and patents and trademarks acquired in connection with our acquisition of DHI. Amortization of intangible assets from acquired technology consists primarily of expense associated with purchased technology.

Other Income (Expense)

Interest expense primarily relates to interest paid on borrowings under the Senior Credit Facility and interest paid on our lease obligation associated with our San Diego facility. The reduction in the outstanding principal balance under the line of credit from $42.0 million as of December 31, 2011 to $5.0 million as of December 31, 2012 resulted in a reduction to interest expense of $0.8 million for the year ended December 31, 2012.

Income Taxes

The effective tax rate for the years ended December 31, 2012 and 2011 were 34.4 % and 33.5%, respectively. We recognized income tax expense of $2.6 million and $3.9 million for the years ended December 31, 2012 and 2011, respectively. For December 31, 2012, the Company's effective tax rate was higher largely as a result of the expiration of the federal tax credit for research and development activities. For December 31, 2011, income tax expense includes a reduction primarily related to the use of research and development credits, partially offset by the loss of manufacturing credits due to the utilization of net operating loss carryforwards.

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

Comparison of years ended December 31, 2011 and 2010

Total Revenues

The following table compares total revenues for the years ended December 31, 2011 and 2010 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2011	2010	$	%
Infectious disease net product sales	$112,227	$68,869	$43,358	63%
Women's health net product sales	32,715	32,246	469	1%
Gastrointestinal disease net product sales	6,920	5,967	953	16%
Other net product sales	4,322	3,864	458	12%
Royalty, license fees and grant revenue	2,419	2,393	26	1%
Total revenues	$158,603	$113,339	$45,264	40%

For the year ended December 31, 2011, total revenue increased 40% to $158.6 million from $113.3 million for the year ended December 31, 2010. The increase in total revenues was primarily due to a more normalized cold and flu season in 2011 and the related increase in sales of our influenza products, as compared to the lack of an influenza season in 2010. Additionally, the increase was due to the first quarter of 2011 including a full quarter of revenues from the DHI acquisition compared to the first quarter of 2010 that does not include $5.7 million of DHI pre-acquisition revenues and increased revenues from our Strep A products.

The revenue from our royalty, license fees and grant revenue category for all periods primarily relate to royalty payments earned on our patented technologies utilized by third parties and revenue from grants for research and commercialization activities.

Cost of Sales

Cost of sales increased 19.5% to $62.9 million, or 40% of total revenues, for the year ended December 31, 2011 compared to $52.6 million, or 46% of total revenues, for the year ended December 31, 2010. The absolute dollar increase in cost of sales is primarily related to the variable nature of direct costs (material and labor) associated with the 40% increase in total revenues, the $0.7 million in 2011 related to the Alere Amendment as discussed in Note 6 in the Notes to Consolidated Financial Statements included in this Annual Report, and $0.6 million in 2011 related to a disposal of inventory associated with a discontinued product. Partially offsetting this increase are acquisition related synergies including certain decreased material costs and freight rates associated with leveraging our combined volume, and reduced overhead costs and scrap at DHI. The decrease in cost of sales as a percentage of total revenue was primarily due to a more favorable product mix, as well as the improved cost structure noted above. Also, 2010 cost of sales includes $1.1 million of costs for the amortization of an inventory fair value adjustment associated with our acquisition of DHI.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2011 and 2010 (in thousands, except percentages):

	For the year ended December 31,					
	2011		2010		Increase (decrease)	
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues	$	%
Research and development	$26,325	17%	$23,696	21%	$2,629	11%
Sales and marketing	25,751	16%	23,972	21%	1,779	7%
General and administrative	22,798	14%	19,346	17%	3,452	18%
Amortization of intangible assets from acquired businesses and technology	7,124	4%	6,731	6%	393	6%
Business acquisition and integration costs, and restructuring charges	—	—	2,276	2%	(2,276)	(100)%

Research and Development Expense

Research and development expense increased from $23.7 million to $26.3 million for the year ended December 31, 2011 primarily related to it including a full year of expense from the DHI acquisition of $1.5 million. In 2011, we had increased expenses associated with the development of potential new technologies and products, as well as impairment charges of $1.1 million and $0.5 million related to a discontinued product and discontinued research and development project, respectively. The overall increase was partially offset by a reversal of a liability related to a technology license.

Sales and Marketing Expense

Sales and marketing expense increased from $24.0 million to $25.8 million primarily related to additional investments in our sales organization and increased commissions associated with higher sales in 2011 of $1.0 million. Also, 2011 includes a full year of expense from the DHI acquisition of $0.5 million. Other key components of this expense relate to continued investment in assessing future product extensions and enhancements and market research.

General and Administrative Expense

General and administrative expense increased from $19.3 million to $22.8 million primarily related to an employee incentive compensation accrual in 2011 of $2.1 million as compared to no bonus accrual in 2010. In addition, 2011 includes an increase in stock-based compensation related to restricted stock awards. Also, 2011 includes a full year of expense from the DHI acquisition of $0.7 million.

Amortization of Intangible Assets from Acquired Businesses and Technology

Amortization of intangible assets from acquired businesses consists of purchased technology, customer relationships and patents and trademarks acquired in connection with the acquisition of DHI. Amortization of intangible assets from licensed technology consists primarily of expense associated with purchased technology. The amortization of intangible assets increased $0.4 million to $7.1 million in 2011 as a result of a full year of amortization from the DHI acquisition, partially offset by a license that became fully amortized in 2010.

Business Acquisition and Integration Costs, and Restructuring Charges

We incurred $2.3 million in expenses during the fiscal year ended December 31, 2010 primarily related to professional fees for the DHI acquisition and integration activities.

Other Income (Expense)

Interest income is comprised of interest earned on our cash and cash equivalents. Interest expense primarily relates to interest paid on borrowings under the Senior Credit Facility and interest paid on our lease obligation associated with our San Diego facility.

Income Taxes

The effective tax rate for the years ended December 31, 2011 and 2010 were 33.5% and 35.3%, respectively. We recognized income tax expense of $3.9 million for the year ended December 31, 2011 compared to an income tax benefit of $6.1 million for the year ended December 31, 2010. For December 31, 2011, income tax expense includes a reduction primarily related to the use of research and development credits, partially offset by the loss of manufacturing credits due to the utilization of net operating loss carryforwards. For the year ended December 31, 2010, the income tax benefit includes a charge related to the re-valuation of our deferred tax assets due to a change in California state tax law regarding income apportionment. Additionally, the effective tax rate in 2010 was impacted by certain acquisition related non-deductible transaction costs and reversing a portion of a tax benefit recognized in 2009 relating to our production deduction.

Liquidity and Capital Resources

As of December 31, 2012 and 2011, our principal sources of liquidity consisted of the following (in thousands):

	December 31,	
	2012	2011
Cash and cash equivalents	$14,856	$61,332
Restricted cash included in prepaid expenses and other current assets	2,156	—
Cash, cash equivalents, and restricted cash	$17,012	$61,332
Working capital including cash, cash equivalents, and restricted cash	$51,611	$71,452
Amount available to borrow under the Senior Credit Facility	$110,359	$74,579

During the year ended December 31, 2012, we received cash, pursuant to a grant agreement, which was restricted as to use until expenditures contemplated in the grant are made. As of December 31, 2012, we recorded this restricted cash as a component of prepaid expenses and other current assets as we anticipate making expenditures under the grant in 2013. The amount available to us under our Senior Credit Facility can fluctuate from time to time due to, among other factors, our funded debt to adjusted EBITDA ratio.

Cash provided by operating activities was $19.6 million during the year ended December 31, 2012. We had net income of $5.0 million, including non-cash charges of $29.9 million of depreciation and amortization of intangible assets and property and equipment, and stock-based compensation. The most significant change in operating assets and liabilities was an increase in accounts receivable of $17.9 million related to the early start to the 2012/2013 cold and flu season in the fourth quarter of 2012. Cash provided by operating activities was $47.5 million during the year ended December 31, 2011. We had net income of $7.6 million, including non-cash charges of $25.3 million of depreciation and amortization of intangible assets and property and equipment, and stock-based compensation. The most significant changes in operating assets and liabilities in 2011 included a decrease in inventories and income tax receivable of $3.4 million and $8.2 million, respectively. The decrease in inventory is related to the seasonal nature of our influenza business, while the decrease in income tax receivable is due to a tax refund received in 2011. Cash used for our operating activities was $10.2 million during the year ended December 31, 2010. We had a net loss of $11.3 million, including non-cash charges of $12.3 million of depreciation and amortization of intangible assets and property and equipment. Other changes in operating assets and liabilities included a decrease in income taxes payable of $6.2 million primarily as a result of tax payments made during the year ended December 31, 2010 as a result of higher taxable earnings in 2009. Accrued royalties decreased by $3.5 million reflecting the lower revenue base on which we pay royalties. The decrease in other current and non-current liabilities of $4.6 million reflects lower customer incentives related to the decrease in revenues that are eligible for volume discounts for the year ended December 31, 2010 compared to the year ended December 31, 2009.

Our investing activities used $28.6 million during the year ended December 31, 2012 primarily related to the acquisition of intangibles associated with our exercise of a buyout clause under the Alere Amendment. During the year ended December 31, 2012, we exercised the buy-out right under the Alere Amendment, which allowed us to buy-out any remaining future royalty obligation for a fixed cash payment in the amount of $15.7 million less $1.0 million of specified third quarter 2011 royalties. In addition, we used $12.2 million of cash for investing activities associated with the acquisition of production and scientific equipment, and building improvements during the year ended December 31, 2012. Our investing activities used $21.1 million during the year ended December 31, 2011 primarily related to $14.0 million for the acquisition

of licensed technology associated with the Alere Amendment as discussed in Note 6 in the Notes to Consolidated Financial Statements included in this Annual Report. In addition, we acquired production and scientific equipment and building improvements during the year ended December 31, 2011 of $4.9 million. Also in 2011, we capitalized $1.3 million of software development costs as part of the acquisition of intangible assets. Our investing activities used $134.6 million during the year ended December 31, 2010 primarily related to the purchase of DHI. In addition, we used approximately $6.5 million for the acquisition of production and scientific equipment and building improvements. We had investments in property, plant and equipment of $0.4 million which had not been paid as of December 31, 2010. These uses of cash were partially offset by proceeds of $4.0 million as a result of the sale of our marketable securities during the year ended December 31, 2010.

We are currently planning approximately $18.3 million in capital expenditures over the next 12 months. The primary purpose for our capital expenditures is to acquire manufacturing and scientific equipment, to purchase or develop information technology, and to implement facility improvements. We plan to fund these capital expenditures with cash flow from operations and other available sources of liquidity. We have $4.7 million in firm purchase commitments with respect to such planned capital expenditures as of December 31, 2012.

Our financing activities used approximately $37.5 million of cash during the year ended December 31, 2012. This was primarily related to repayments under our Senior Credit Facility and other debt payments of $38.5 million and repurchases of 231,700 shares of our common stock primarily under our share repurchase program at a cost of $2.9 million, and was partially offset by proceeds from the sale of our common stock of $4.7 million. Our financing activities generated approximately $28.1 million of cash during the year ended December 31, 2011. This was primarily related to proceeds from the sale of our common stock, partly offset by repayments made under the Senior Credit Facility, both of which occurred during the first quarter of 2011. Our financing activities generated approximately $62.6 million of cash during the year ended December 31, 2010. This was primarily related to our borrowing of $75.0 million under the Senior Credit Facility (as defined below) in connection with the acquisition of DHI, which was partially offset by our repurchase of 740,177 shares of our common stock at a cost of approximately $9.2 million and re-payments on our borrowing from the Senior Credit Facility of $3.0 million.

On August 10, 2012, we entered into an amended and restated $140.0 million Senior Credit Facility, which matures on August 10, 2017. On August 10, 2012, we entered into the Senior Credit Facility, which matures on August 10, 2017. The Senior Credit Facility amends and restates our $120.0 million senior secured credit facility dated October 8, 2008. As part of this amendment, we incurred $1.0 million in deferred financing costs related to the Senior Credit Facility in addition to the $0.6 million we had previously recorded related to the original credit facility. As of December 31, 2012, we had $1.5 million of deferred financing costs included as a portion of other non-current assets. The Senior Credit Facility bears interest at either LIBOR or the base rate, plus, in each case, the applicable margin. The base rate is equal to the highest of (i) the lender's prime rate, (ii) the federal funds rate plus one-half of one percent and (iii) LIBOR plus one percent. The applicable margin is generally determined in accordance with a performance pricing grid based on our leverage ratio and ranges from 1.25% to 2.50% for LIBOR rate loans and from 0.25% to 1.50% for base rate loans (weighted average interest rate of 1.46% at December 31, 2012). The agreement governing the Senior Credit Facility is subject to certain customary limitations, including among others: limitation on liens; limitation on mergers, consolidations and sales of assets; limitation on debt; limitation on dividends, stock redemptions and the redemption and/or prepayment of other debt; limitation on investments (including loans and advances) and acquisitions; limitation on transactions with affiliates; and limitation on disposition of assets. We are also subject to financial covenants which include a funded debt to adjusted EBITDA ratio (as defined in the Senior Credit Facility) not to exceed 3:1 as of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:1 as of the end of each fiscal quarter. The Senior Credit Facility is secured by substantially all of our present and future assets and properties. Our ability to borrow under the Senior Credit Facility fluctuates from time to time due to, among other factors, our borrowings under the facility and our funded debt to adjusted EBITDA ratio. At December 31, 2012, we had $5.0 million outstanding under the Senior Credit Facility. As of December 31, 2012, we were in compliance with all financial covenants.

Our cash requirements fluctuate as a result of numerous factors, such as the extent to which we generate cash from operations, progress in research and development projects, competition and technological developments and the time and expenditures required to obtain governmental approval of our products. In addition, we intend to continue to evaluate candidates for acquisitions or technology licensing. If we determine to proceed with any such transactions, we may need to incur additional debt, or issue additional equity, to successfully complete the transactions. Based on our current cash position and our current assessment of future operating results, we believe that our existing sources of liquidity will be adequate to meet our operating needs during the next 12 months.

Off-Balance Sheet Arrangements

At December 31, 2012 and 2011, we did not have any relationships with unconsolidated entities or financial partners, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

Contractual Obligations

As of December 31, 2012, our future contractual obligations were as follows (in thousands):

	Payment due by period				
	Total	Less than 1 year	1-3 Years	3-5 Years	More than 5 years
Lease obligation(1)	$8,006	$1,117	$2,259	$2,297	$2,333
Operating lease obligations(2)	4,917	1,747	2,196	974	—
Non-cancellable purchase commitments(3)	4,702	4,702	—	—	—
Borrowing under line of credit(4)	5,000	—	—	5,000	—
Total contractual obligations	$22,625	$7,566	$4,455	$8,271	$2,333

(1) Reflects our lease obligation on the approximately 78,000 square-foot San Diego facility in place as of December 31, 2012. The facility is subject to a financing arrangement with payments through December 2019. Our future obligation under this financing arrangement is included in the table above.

(2) Reflects obligations on facilities and equipment under operating leases in place as of December 31, 2012. In the fourth quarter of 2011, we entered into a new operating lease to rent approximately 11,000 square feet of additional office space in San Diego with a lease term through October 2013. The operating lease at our Santa Clara location has a lease term through November 2014. In the fourth quarter of 2011, we exercised our renewal option at the Athens, Ohio location. The amended lease expires in 2017 with two options to extend the lease for additional five-year periods through 2027. Future minimum lease payments are included in the table above.

(3) Reflects our $4.7 million of non-cancellable commitments to purchase property, plant and equipment under contractual arrangements.

(4) Reflects our $5.0 million borrowing under the secured revolving line of credit which is scheduled to expire on August 10, 2017.

We have entered into various licensing agreements, which largely require payments based on specified product sales as well as the achievement of specific milestones. Royalty and license expenses under these various royalty and licensing agreements collectively totaled $9.4 million, $10.9 million and $7.8 million for the years ended December 31, 2012, 2011 and 2010, respectively including $8.4 million, $4.0 million, and $0.1 million in amortization expense for 2012, 2011 and 2010, 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.

We exclude liabilities pertaining to uncertain tax positions from our summary of contractual obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities, nor the amount of the final cash settlement. As of December 31, 2012 we had approximately $4.5 million of liabilities associated with uncertain tax positions.

New Accounting Standards

In June 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* ("ASU 2011-05"). The provisions of this ASU amend FASB Accounting Standards Codification ("ASC") Topic 220, Comprehensive Income, to facilitate the continued alignment of U.S. GAAP with International Accounting Standards. ASU 2011-05 prohibits the presentation of the components of comprehensive income in the statement of stockholders' equity. Reporting entities are allowed to present either: a statement of comprehensive income, which reports both net income and other comprehensive income; or separate, but consecutive, statements of net income and other comprehensive income. Under previous GAAP, all three presentations

were acceptable. Regardless of the presentation selected, the Reporting Entity is required to present all reclassifications between other comprehensive and net income on the face of the new statement or statements. We have incorporated ASU No. 2011-05 into this annual filing.

In September 2011, the FASB issued ASU No. 2011-08, *Intangibles—Goodwill and Other (Topic 350): Testing Goodwill for Impairment*, ("ASU 2011-08"), to allow entities to use a qualitative approach to test goodwill for impairment. ASU 2011-08 permits an entity to first perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If it is concluded that this is the case, it is necessary to perform the currently prescribed two-step goodwill impairment test. Otherwise, the two-step goodwill impairment test is not required. The provisions of this ASU were effective for us for fiscal years and interim periods beginning after December 31, 2011, and the adoption did not have an impact on our consolidated financial statements.

In July 2012, the FASB issued ASU No. 2012-02, *Intangibles—Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*, ("ASU 2012-02"), to simplify the testing for a drop in value of intangible assets such as trademarks, patents, and distribution rights. The amended standard reduces the cost of accounting for indefinite-lived intangible assets, especially in cases where the likelihood of impairment is low. The changes permit businesses and other organizations to first use subjective criteria to determine if an intangible asset has lost value. The amendments to U.S. GAAP will be effective for fiscal years starting after September 15, 2012. Early adoption is permitted. We are currently evaluating the impact of our pending adoption of ASU 2012-02 on our consolidated financial statements.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to customer programs and incentives, bad debts, inventories, intangible assets, income taxes, stock-based compensation, restructuring and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

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

We earn income from grants for research and commercialization activities. On November 6, 2012, we were awarded a milestone-based grant totaling up to $8.3 million from the Bill and Melinda Gates Foundation to develop, manufacture and validate a quantitative, low-cost, nucleic acid assay for HIV drug treatment monitoring on the integrated Savanna™ MDx platform for use in limited resource settings. Upon execution of the grant agreement, we received $2.6 million to fund subsequent research and development activities. We expect to receive milestone payments of $2.5 million in 2013 and $3.2 million in 2014 and will recognize grant revenue on the lessor of the amount recognized on a straight-line basis or the amount that is non-refundable through the end of the agreement, which is December 31, 2015. For the year ended December 31, 2012, we recognized $0.4 million as grant revenue and have included $2.2 million of restricted cash as a component of prepaid expense and other current assets and as a component of other current liabilities.

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

Stock-Based Compensation

Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option award. The total number of stock options expected to vest is adjusted by estimated forfeiture rates. We determine the estimated fair value of each stock option on the date of grant using the Black-Scholes option valuation model. Compensation expense for time-based restricted stock awards and units is measured at the grant date and recognized ratably over the vesting period. We determine the fair value of time-based and performance-based restricted stock based on the closing market price of our common stock on the grant date. A portion of the restricted stock granted in 2012 and 2011 was performance-based and vesting is tied to achievement of specific Company goals in 2014 and 2013. For purposes of measuring compensation expense, we estimate the amount of shares ultimately expected to vest at each reporting date based on management's expectations regarding achievement of the relevant performance criteria. The recognition of compensation expense associated with performance-based restricted stock requires judgment in assessing the probability of meeting the performance goals, as well as defined criteria for assessing achievement of the performance-related goals. This may result in significant expense recognition in the period in which the performance goals are met or when achievement of the goals is deemed probable or may result in the reversal of previously recognized stock-based compensation expense if the performance criteria are deemed not probable of being met. The grant date of the performance-based restricted stock takes place when the grant is authorized and the specific achievement goals are communicated. The communication date of the performance goals can impact the valuation and associated expense of the restricted stock.

The computation of the expected option life is based on a weighted-average calculation combining the average life of options that have already been exercised and post-vest cancellations with the estimated life of the remaining vested and unexercised options. The expected volatility is based on the historical volatility of our stock. The risk-free interest rate is based on the U.S Treasury yield curve over the expected term of the option. We have never paid any cash dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future. Consequently, we use an expected dividend yield of zero in the Black-Scholes option valuation model. The estimated forfeiture rate is based on our historical experience and future expectations.

Reserve for Uncollectible Accounts Receivable

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

Inventory

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

Intangible Assets

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

- the asset’s ability to continue to generate income from operations and positive cash flow in future periods;
- any volatility or significant decline in our stock price and market capitalization compared to our net book value;
- loss of legal ownership or title to an asset;

- significant changes in our strategic business objectives and utilization of our assets; and

- the impact of significant negative industry or economic trends.

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

For goodwill, a two-step test is used to identify the potential impairment and to measure the amount of impairment, if any. The first step is to compare the fair value of a reporting unit with the carrying amount, including goodwill. If the fair value of a reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, goodwill is impaired and the loss is measured by performing step two. Under step two, the impairment loss is measured by comparing the implied fair value of the reporting unit with the carrying amount of goodwill. We are required to perform periodic evaluations for impairment of goodwill balances. We completed our annual evaluation for impairment of goodwill and in-process research and development as of December 31, 2012 and determined that no impairment existed.

Determining the initial fair values and useful lives of the intangible assets acquired in connection with the Alere Amendment described in Note 6 in the Notes to Consolidated Financial Statements included in this Annual Report required the exercise of judgment. While there are a number of different generally accepted valuation methods to estimate the value of intangible assets, we used the discounted cash flow method in determining the value of licensed technology associated with the Alere Amendment. This method required significant management judgment to forecast the future operating results used in the analysis. In addition, other significant estimates were required such as residual growth rates and discount factors. The estimates we used to value and amortize intangible assets were consistent with the plans and estimates that we use to manage our business and were based on available historical information and industry estimates and averages. These judgments can significantly affect our net operating results.

Software Development Costs

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

Income Taxes

Significant judgment is required in determining our provision for income taxes, current tax assets and liabilities, deferred tax assets and liabilities, and our future taxable income, both as a whole and in various tax jurisdictions, for purposes of assessing our ability to realize future benefit from our deferred tax assets. A valuation allowance may be established to reduce our deferred tax assets to the amount that is considered more likely than not to be realized through the generation of future taxable income and other tax planning opportunities. Based on the required adoption of the California single sales factor, our tax rate in California may be lower in the future. In determining the need for a valuation allowance, the factors reviewed include projections of California pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting. While we concluded that it is more likely than not that we will be able to utilize our California deferred tax assets, there is significant judgment involved. To the extent that a determination is made to establish or adjust a valuation allowance, the expense or benefit is recorded in the period in which the determination is made. We will continue to assess the need for a valuation allowance on our deferred tax assets by evaluating both positive and negative evidence that may exist.

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

We recognize excess tax benefits associated with the exercise of stock options directly to stockholders' equity only when realized. Accordingly, deferred tax assets are not recognized for net operating loss carryforwards resulting from excess tax benefits. As of December 31, 2012 and 2011, deferred tax assets do not include $1.1 million and $2.3 million,

respectively of these excess tax benefits from employee stock option exercises that are a component of our net operating loss carryforwards. Additional paid-in capital would be increased up to $1.1 million if such excess tax benefits are realized.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The fair market value of our floating interest rate debt is subject to interest rate risk. Generally, the fair market value of floating interest rate debt will vary as interest rates increase or decrease. We had $5.0 million outstanding under our Senior Credit Facility at December 31, 2012. The weighted average interest rate on these borrowings is currently 1.46%. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would increase our annual interest expense by approximately $0.1 million. Based on our market risk sensitive instruments outstanding at December 31, 2012 and 2011, we have determined that there was no material market risk exposure from such instruments to our consolidated financial position, results of operations or cash flows as of such dates.

Our current investment policy with respect to our cash and cash equivalents focuses on maintaining acceptable levels of interest rate risk and liquidity. Although we continually evaluate our placement of investments, as of December 31, 2012, our cash and cash equivalents were placed in money market or overnight funds that we believe are highly liquid and not subject to material market fluctuation risk.

Foreign Currency Exchange Risk

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

Item 8. Financial Statements and Supplementary Data

The consolidated financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15(a)(1) and are incorporated herein.

Part III

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

None.

Item 9A. Controls and Procedures

Evaluation of disclosure controls and procedures: We have performed an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"). Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of December 31, 2012 to provide reasonable assurance that information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in internal control over financial reporting: There was no change in our internal control over financial reporting during the three months ended December 31, 2012 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting: Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2012.

The effectiveness of our internal control over financial reporting as of December 31, 2012 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included in this Item 9A.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and
Stockholders of Quidel Corporation

We have audited Quidel Corporation's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("the COSO criteria"). Quidel Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, Quidel Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Quidel Corporation as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2012 of Quidel Corporation and our report dated February 22, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 22, 2013

Item 9B. Other Information

2013 Annual Meeting of Stockholders

The Company's 2013 Annual Meeting of Stockholders will be held on Tuesday, May 14, 2013, beginning at 8:30 a.m. (local time) at the San Diego Marriott Del Mar, 11966 El Camino Real, San Diego, California, 92130.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item (with respect to directors) is incorporated by reference from the information under the caption "Election of Directors" to be contained in our 2013 Proxy Statement, which will be filed with the SEC no later than April 30, 2013. Information with respect to executive officers is included under Item 1 on pages 11-12 of this Annual Report.

The information required by Items 405, 406 and 407 of Regulation S-K is incorporated by reference from the information under the captions "Corporate Governance" and "Section 16(a) Beneficial Ownership Reporting Compliance," to be contained in our 2013 Proxy Statement, which will be filed with the SEC no later than April 30, 2013.

Item 11. Executive Compensation

The information required by this item is incorporated by reference from the information under the captions "Director Compensation" and "Executive Compensation" to be contained in our 2013 Proxy Statement, which will be filed with the SEC no later than April 30, 2013.

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

The information required by Items 201(d) and 403 of Regulation S-K is incorporated by reference from the information under the captions "Securities Available for Issuance Under Our Equity Compensation Plans" and "Security Ownership of Certain Beneficial Owners and Management" to be contained in our 2013 Proxy Statement, which will be filed with the SEC no later than April 30, 2013.

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

The information required by this item is incorporated by reference from the information under the captions "Compensation Committee Interlocks and Insider Participation in Compensation Decisions," "Certain Relationships and Related Transactions" and "Corporate Governance" to be contained in our 2013 Proxy Statement, which will be filed with the SEC no later than April 30, 2013.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference from the information under the caption "Audit Committee Matters" to be contained in our 2013 Proxy Statement, which will be filed with the SEC no later than April 30, 2013.

Part IV

Item 15. Exhibits and Financial Statement Schedules

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

(a) (1) Financial Statements

The Consolidated Financial Statements required by this Item are submitted in a separate section beginning on page F-1 of this Annual Report and incorporated herein by reference.

Consolidated Financial Statements of Quidel Corporation

(2) Financial Statement Schedules

The following Financial Statement Schedule of Quidel Corporation for the years ended December 31, 2012, 2011 and 2010 is filed as part of this Annual Report and should be read in conjunction with the Consolidated Financial Statements of Quidel Corporation:

Schedule II. Consolidated Valuation and Qualifying Accounts.

Financial Statement Schedules not listed above have been omitted because of the absence of conditions under which they are required or because the required information is included in the Consolidated Financial Statements or the Notes thereto.

(3) Exhibits. See Paragraph 15(b) below.

(b) Exhibits

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

(c) Financial Statements required by Regulation S-X which are excluded from this Annual Report on Form 10-K by Rule 14(a)-3(b).

Not applicable.

SIGNATURES

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

QUIDEL CORPORATION

Date: February 22, 2013

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

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

Signature	Title	Date
/s/ DOUGLAS C. BRYANT Douglas C. Bryant	President, Chief Executive Officer (Principal Executive Officer), and Director	February 22, 2013
/s/ RANDALL J. STEWARD Randall J. Steward	Chief Financial Officer, (Principal Financial Officer and Accounting Officer)	February 22, 2013
/s/ MARK A. PULIDO Mark A. Pulido	Chairman of the Board	February 22, 2013
/s/ THOMAS D. BROWN Thomas D. Brown	Director	February 22, 2013
/s/ KENNETH F. BUECHLER Kenneth F. Buechler	Director	February 22, 2013
/s/ RODNEY F. DAMMEYER Rodney F. Dammeyer	Director	February 22, 2013
/s/ MARY LAKE POLAN Mary Lake Polan	Director	February 22, 2013
/s/ JACK W. SCHULER Jack W. Schuler	Director	February 22, 2013

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and
Stockholders of Quidel Corporation

We have audited the accompanying consolidated balance sheets of Quidel Corporation as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2012. Our audits also included the financial statement schedule listed in the Index at Item 15(a)(2). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Quidel Corporation at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Quidel Corporation's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 22, 2013 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Diego, California
February 22, 2013

QUIDEL CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except par value)

	December 31,	
	2012	2011
ASSETS		
Current assets:		
Cash and cash equivalents	$14,856	$61,332
Accounts receivable, net	32,570	14,646
Inventories	15,496	14,306
Deferred tax asset—current	6,622	10,681
Prepaid expenses and other current assets	5,228	3,413
Total current assets	74,772	104,378
Property, plant and equipment, net	34,156	28,434
Goodwill	71,013	71,013
Intangible assets, net	60,341	73,830
Other non-current assets	1,817	1,239
Total assets	$242,099	$278,894
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$7,864	$5,001
Accrued payroll and related expenses	6,016	5,377
Accrued royalties	252	15,093
Current portion of lease obligation	380	329
Other current liabilities	8,649	7,126
Total current liabilities	23,161	32,926
Long term debt	5,000	42,000
Lease obligation, net of current portion	5,567	5,947
Deferred tax liability—non-current	3,349	7,040
Income taxes payable	4,548	4,667
Other non-current liabilities	694	928
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $.001 par value per share; 5,000 shares authorized, none issued or outstanding at December 31, 2012 and 2011	—	—
Common stock, $.001 par value per share; 50,000 shares authorized, 33,452 and 33,276 shares issued and outstanding at December 31, 2012 and 2011, respectively	33	33
Additional paid-in capital	184,431	175,030
Retained earnings	15,316	10,323
Total stockholders' equity	199,780	185,386
Total liabilities and stockholders' equity	$242,099	$278,894

See accompanying notes.

QUIDEL CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year ended December 31,		
	2012	2011	2010
Total revenues	$155,741	$158,603	$113,339
Costs and expenses			
Cost of sales (excludes amortization of intangible assets of $5,753, $6,667 and $5,852, respectively)	61,285	62,865	51,489
Amortization of inventory fair value adjustment from acquisition	—	—	1,118
Total cost of sales (excludes amortization of intangible assets of $5,753, $6,667 and $5,852, respectively)	61,285	62,865	52,607
Research and development	27,716	26,325	23,696
Sales and marketing	30,319	25,751	23,972
General and administrative	20,640	22,798	19,346
Amortization of intangible assets from acquired businesses and technology	6,935	7,124	6,731
Business acquisition and integration costs, and restructuring charges	—	—	2,276
Total costs and expenses	146,895	144,863	128,628
Operating income (loss)	8,846	13,740	(15,289)
Other (expense) income			
Interest income	41	203	214
Interest expense	(1,246)	(2,083)	(2,345)
Other expense	(30)	(376)	—
Total other expense	(1,235)	(2,256)	(2,131)
Income (loss) before provision (benefit) for taxes	7,611	11,484	(17,420)
Provision (benefit) for income taxes	2,618	3,851	(6,149)
Net income (loss)	$4,993	$7,633	$(11,271)
Basic and diluted earnings (loss) per share	$0.15	$0.23	$(0.39)
Shares used in basic per share calculations	33,068	32,903	28,582
Shares used in diluted per share calculations	33,702	33,320	28,582

See accompanying notes.

QUIDEL CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(in thousands)

	Year ended December 31,		
	2012	2011	2010
Net income (loss)	$4,993	$7,633	$(11,271)
Other comprehensive loss, net of tax			
Realized loss on marketable securities, net of income tax benefit of $12	—	—	(34)
Total other comprehensive loss	—	—	(34)
Comprehensive income (loss)	$4,993	$7,633	$(11,305)

See accompanying notes.

QUIDEL CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands)

	Common Stock					
	Shares	Par	Additional paid-in capital	Accumulated other comprehensive income	Retained earnings	Total stockholders' equity
Balance at December 31, 2009	29,026	$29	$112,426	$34	$13,961	$126,450
Issuance of common stock under equity compensation plans	310	1	1,151	—	—	1,152
Cancellation of common stock under equity compensation plans	(82)	—	(1)	—	—	(1)
Income tax benefit due to exercise/disposition of employee stock options	—	—	248	—	—	248
Stock-based compensation expense	—	—	5,158	—	—	5,158
Unrealized loss on marketable securities	—	—	—	(34)	—	(34)
Repurchase of common stock	(740)	(1)	(9,180)	—	—	(9,181)
Net loss	—	—	—	—	(11,271)	(11,271)
Balance at December 31, 2010	28,514	29	109,802	—	2,690	112,521
Issuance of common stock under equity compensation plans	236	—	2,018	—	—	2,018
Issuance of common stock through public offering, net of issuance costs of $662	4,600	5	57,220	—	—	57,225
Cancellation of common stock under equity compensation plans	(31)	(1)	—	—	—	(1)
Income tax benefit due to exercise/disposition of employee stock options	—	—	12	—	—	12
Stock-based compensation expense	—	—	6,603	—	—	6,603
Repurchase of common stock	(43)	—	(625)	—	—	(625)
Net income	—	—	—	—	7,633	7,633
Balance at December 31, 2011	33,276	33	175,030	—	10,323	185,386
Issuance of common stock under equity compensation plans	415	—	5,581	—	—	5,581
Cancellation of common stock under equity compensation plans	(9)	—	—	—	—	—
Income tax benefit due to exercise/disposition of employee stock options	—	—	1,102	—	—	1,102
Stock-based compensation expense	—	—	6,125	—	—	6,125
Repurchase of common stock	(231)	—	(3,407)	—	—	(3,407)
Net income	—	—	—	—	4,993	4,993
Balance at December 31, 2012	33,451	$33	$184,431	$—	$15,316	$199,780

See accompanying notes.

QUIDEL CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2012	2011	2010
	(in thousands)		
OPERATING ACTIVITIES			
Net income (loss)	$4,993	$7,633	$(11,271)
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:			
Depreciation, amortization and other	23,261	17,809	12,326
Stock-based compensation expense	6,598	7,500	5,158
Impairment of long-lived and intangible assets	—	1,643	—
Loss on disposal of property, plant and equipment	101	368	9
Change in deferred tax assets and liabilities	1,469	1,217	1,273
Excess tax benefit from share-based compensation	(1,102)	(12)	(248)
Changes in assets and liabilities:			
Accounts receivable	(17,924)	(1,169)	3,079
Inventories	(1,075)	3,401	2,420
Income tax receivable	167	8,177	(4,196)
Prepaid expenses and other current and non-current assets	(2,042)	(340)	771
Accounts payable	1,545	126	(2,595)
Accrued payroll and related expenses	1,083	1,317	(2,636)
Accrued royalties	(125)	(1,998)	(3,515)
Accrued income taxes payable	(119)	1,730	(6,151)
Other current and non-current liabilities	2,803	139	(4,636)
Net cash provided by (used for) operating activities	19,633	47,541	(10,212)
INVESTING ACTIVITIES			
Acquisitions of property and equipment	(12,221)	(4,853)	(6,486)
Purchase of business, net of cash acquired of $- for 2012 and $3,150 for 2010	(1,000)	—	(128,142)
Proceeds from sale of marketable securities	—	—	3,999
Proceeds from sale of fixed assets	122	—	—
Acquisition of intangibles	(15,501)	(16,282)	(3,991)
Net cash used for investing activities	(28,600)	(21,135)	(134,620)
FINANCING ACTIVITIES			
Proceeds from issuance of common stock, net of cancellations	4,664	59,243	1,151
Excess tax benefit from share-based compensation	1,102	12	248
Payments on lease obligation	(329)	(280)	(205)
Repurchases of common stock	(3,407)	(626)	(9,181)
Borrowing from line of credit	—	—	75,000
Payments on line of credit	(37,000)	(30,000)	(3,000)
Payments on note payable to state agency	(1,498)	(211)	(177)
Other	(1,041)	—	(1,219)
Net cash (used for) provided by financing activities	(37,509)	28,138	62,617
Net (decrease) increase in cash and cash equivalents	(46,476)	54,544	(82,215)
Cash and cash equivalents at beginning of year	61,332	6,788	89,003
Cash and cash equivalents at end of year	$14,856	$61,332	$6,788
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid for interest	$1,246	$2,083	$2,345
Cash paid for income taxes	$—	$350	$7,711
NON-CASH INVESTING ACTIVITIES			
Purchase of licensed technology by incurring current liabilities	$108	$14,829	$800
Purchase of capital equipment by incurring current liabilities	$1,086	$160	$401
NON-CASH FINANCING ACTIVITIES			
Reduction of other non-current assets upon issuance of common stock	$—	$478	$—
Reduction of other current liabilities upon issuance of restricted share units	$917	$—	$—

See accompanying notes.

QUIDEL CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Company Operations and Summary of Significant Accounting Policies

Quidel Corporation (the "Company") commenced operations in 1979. The Company operates in one business segment, which develops, manufactures and markets rapid diagnostic testing solutions. These diagnostic testing solutions primarily include applications in infectious diseases, women's health and gastrointestinal diseases. The Company sells its products directly to end users and distributors, in each case, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, leading universities, retail clinics and wellness screening centers. The Company markets its products in the U.S. through a network of national and regional distributors, and a direct sales force. Internationally, the Company sells and markets primarily in Japan and Europe through distributor arrangements.

The accompanying consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with generally accepted accounting principles in the U.S.

Certain reclassifications have been made to prior year amounts to conform to the current year presentation. The Company reclassified the principal payments on note payable to state agency of $0.2 million on the Consolidated Statements of Cash Flows to financing activities for each of the years ended December 31, 2011 and 2010. The Company reclassified $0.3 million of inventory items to property, plant and equipment on the Consolidated Balance Sheets as of December 31, 2011. The inventory reclassification resulted in an increase in cash flows from operating activities and a decrease to cash used for investing activities of $0.3 million for the year ended December 31, 2011.

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

Cash and Cash Equivalents—The Company considers cash equivalents to be highly liquid investments with a maturity at the date of purchase of three months or less.

Accounts Receivable—The Company sells its products directly to hospitals and reference laboratories in the U.S. as well as to distributors in the U.S., Europe and Japan. The Company periodically assesses the financial strength of these customers and establishes reserves for anticipated losses when necessary, which historically have not been material. The Company's reserves primarily consist of amounts related to cash discounts and contract rebates, and to a lesser extent, bad debts. The balance of accounts receivable is net of reserves primarily related to sales allowances, and to a lesser extent, bad debts of $5.0 million and $2.0 million at December 31, 2012 and 2011, respectively.

Concentration of Credit Risk—Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash and cash equivalents and investments in accounts receivable.

The Company invests its cash equivalents primarily in money market funds. Cash equivalents are maintained with high quality institutions.

The Company's trade accounts receivable are primarily derived from sales to medical distributors, hospitals and reference laboratories in the U.S. (see Note 7). The Company performs credit evaluations of its customers' financial condition and limits the amount of credit extended when deemed necessary, but generally requires no collateral. Credit quality is monitored by evaluation of collection history. The Company believes that the concentration of credit risk in its trade receivables is moderated by its credit evaluation process, relatively short collection terms, the high level of credit worthiness of its customers, and letters of credit issued on the Company's behalf. Potential credit losses are limited to the gross value of accounts receivable.

Inventories—Inventories are stated at the lower of cost (first-in, first-out method) or market. The Company reviews the components of its inventory on a quarterly basis for excess, obsolete and impaired inventory and makes appropriate dispositions as obsolete stock is identified. For the year ended December 31, 2011, the Company recorded $0.6 million in inventory dispositions associated with a discontinued product. Inventories consisted of the following, net of reserves of $0.6 million and $0.5 million at December 31, 2012 and 2011, respectively (in thousands):

Note 1. Company Operations and Summary of Significant Accounting Policies (Continued)

	December 31,	
	2012	2011
Raw materials	$5,582	$5,239
Work-in-process (materials, labor and overhead)	4,686	3,632
Finished goods (materials, labor and overhead)	5,228	5,435
Total inventories	$15,496	$14,306

Property, Plant and Equipment—Property, plant and equipment is recorded at cost and depreciated over the estimated useful lives of the assets (three to 15 years) using the straight-line method. Amortization of leasehold improvements is computed on the straight-line method over the shorter of the lease term or the estimated useful lives of the assets. The total expense for depreciation of fixed assets and amortization of leasehold improvements was $7.3 million, $6.0 million and $5.2 million for the years ended December 31, 2012, 2011 and 2010, respectively. Maintenance and minor repairs are charged to operations as incurred.

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

	December 31,	
	2012	2011
Equipment, furniture and fixtures	$53,626	$46,428
Instruments available for lease	3,872	348
Building and improvements	26,507	26,467
Land	1,080	1,080
	85,085	74,323
Less: Accumulated depreciation and amortization	(50,929)	(45,889)
Total property, plant and equipment, net	$34,156	$28,434

Intangible Assets—Intangible assets are recorded at cost and amortized on a straight-line basis over their estimated useful lives, except for software development costs and indefinite-lived intangibles such as goodwill and in-process research and development. Software development costs associated with software to be sold, leased or otherwise marketed are expensed as incurred until technological feasibility has been established. After technological feasibility is established, software development costs are capitalized. The capitalized cost is amortized on a straight-line basis over the estimated product life or on the ratio of current revenues to total projected product revenues, whichever is greater. The Company capitalized $0.9 million of software costs in 2012 and expects to amortize these costs over a weighted average useful life of five years. Intangible assets consisted of the following (dollar amounts in thousands):

	Weighted-Average Remaining Life (years)	December 31, 2012			December 31, 2011		
Description		Gross Assets	Accumulated Amortization	Net	Gross Assets	Accumulated Amortization	Net
Goodwill	Indefinite	$74,461	$(3,448)	$71,013	$74,461	$(3,448)	$71,013
Purchased technology	5.3	52,670	(22,308)	30,362	52,670	(16,554)	36,116
Customer relationships	5.0	6,322	(2,007)	4,315	5,450	(1,268)	4,182
In-process research and development	Indefinite	1,570	—	1,570	1,570	—	1,570
License agreements	3.1	49,378	(29,386)	19,992	49,378	(20,994)	28,384
Patent and trademark costs	12.1	5,012	(3,887)	1,125	5,012	(3,795)	1,217
Software development costs	4.4	3,262	(391)	2,871	2,323	(124)	2,199
Other	1.8	1,700	(1,594)	106	1,700	(1,538)	162
Total goodwill and intangible assets		$194,375	$(63,021)	$131,354	$192,564	$(47,721)	$144,843

In 2012, the Company acquired a product line for $1.0 million and assigned $0.9 million to customer relationships. The customer relationship asset will be amortized over its expected life of five years.

Note 1. Company Operations and Summary of Significant Accounting Policies (Continued)

Amortization expense was $15.4 million, $11.3 million and $6.7 million for the years ended December 31, 2012, 2011 and 2010, respectively. Included in the $15.4 million of amortization expense for 2012 is $8.0 million of amortization for licensed technology recorded in cost of sales. This amount is related to the purchase of a license as discussed in Note 6. Amortization expense associated with this intangible asset will be recorded in cost of sales and is expected to be $8.0 million per year for fiscal periods 2013 through 2014.

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

Years Ended December 31,	Amortization Expense
2013	$15,721
2014	15,766
2015	8,335
2016	7,552
2017	7,327
Thereafter	4,070
Total	$58,771

The Company completed its annual evaluation for impairment of goodwill and in-process research and development as of December 31, 2012 and determined that no impairment of goodwill and indefinite lived intangible assets existed. The Company recorded a $0.5 million impairment charge of in-process research and development related to a discontinued research and development project for the year ended December 31, 2011. To value this asset, the Company considered a discounted future cash flow model. The Company determined that this asset had no future cash flows associated with it and was fully impaired. The Company classified this impairment loss as research and development expense on the Consolidated Statements of Operations. A significant decline in the Company's projected revenue or earnings growth or cash flows, a significant decline in the Company's stock price or the stock price of comparable companies, loss of legal ownership or title to an asset, and any significant change in the Company's strategic business objectives and utilization of assets are among many factors that could result in an impairment charge that could have a material negative impact on the Company's operating results.

Impairment of Long-Lived Assets—The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the total book value of an asset may not be recoverable. An impairment loss is recognized when estimated undiscounted future cash flows expected to result from the use of the asset and the eventual disposition are less than its carrying amount. An impairment loss is equal to the excess of the book value of an asset over its determined fair value. The Company recorded no impairment charges for the year ended December 31, 2012. For the year ended December 31, 2011, the Company recorded $1.0 million of impairment charges on a fixed asset group related to a discontinued product. To value this asset group, the Company considered a discounted future cash flow model. The Company determined that this asset group had no future cash flows associated with it and was fully impaired. The Company classified this impairment loss as research and development expense on the Consolidated Statements of Operations. The Company recorded no impairment charges for the year ended December 31, 2010.

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

	December 31,	
	2012	2011
Accrued liability for technology licenses	$707	$863
Customer incentives	2,693	2,352
Current portion of note payable to state agency	—	1,498
Unearned grant revenue	2,156	—
Income taxes payable	1,615	595
Other	1,478	1,818
Total other current liabilities	$8,649	$7,126

Note 1. Company Operations and Summary of Significant Accounting Policies (Continued)

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

The Company earns income from grants for research and commercialization activities. On November 6, 2012, the Company was awarded a milestone-based grant totaling up to $8.3 million from the Bill and Melinda Gates Foundation to develop, manufacture and validate a quantitative, low-cost, nucleic acid assay for HIV drug treatment monitoring on the integrated Savanna™ MDx platform for use in limited resource settings. Upon execution of the grant agreement, the Company received $2.6 million to fund subsequent research and development activities. The Company expects to receive milestone payments of $2.5 million in 2013 and $3.2 million in 2014 and will recognize grant revenue on the lessor of the amount recognized on a straight-line basis or the amount that is non-refundable through the end of the agreement, which is December 31, 2015. For the year ended December 31, 2012, the Company recognized $0.4 million as grant revenue and has included $2.2 million of restricted cash as a component of prepaid expense and other current assets and as a component of other current liabilities.

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

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

Collaborative Arrangement—During the year ended December 31, 2012, the Company entered into a collaborative arrangement with Life Technologies for the development of molecular assays over a five year term. ASC Topic 808, Collaborative Arrangements, defines a collaborative arrangement as an arrangement where the parties are active participants and have exposure to significant risks. The Company is accounting for the joint development and commercialization activities with the third-party as a joint risk sharing collaboration in accordance with ASC Topic 808, Collaborative Arrangements. Payments from the third party, which totaled $3.0 million in 2012, are recorded as a reduction to research and development expense in the accompanying consolidated financial statements due to the nature of the activities. In connection with the executed project plan, the third party is expected to reimburse the Company an additional $2.0 million through 2013. The reimbursement represents 50% of project development costs based upon mutually agreed upon project plans for each molecular assay. In connection with the collaboration agreement, the Company also entered into a manufacturing and supply agreement with the same third party. As part of that agreement, and upon commercialization, the Company will manufacture and sell assays to the third party at cost plus 20%. Additionally, the Company will receive 40% of the gross margin for sales from the third party to the end customer.

Product Shipment Costs—Product shipment costs are included in sales and marketing expense in the accompanying Consolidated Statements of Operations. Shipping and handling costs were $1.6 million, $1.6 million and $1.2 million for the years ended December 31, 2012, 2011 and 2010, respectively.

Advertising Costs—Advertising costs are expensed as incurred. Advertising costs were $0.2 million, $0.7 million and $1.0 million for the years ended December 31, 2012, 2011 and 2010, respectively.

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

Note 1. Company Operations and Summary of Significant Accounting Policies (Continued)

Income Taxes—Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

Fair Value of Financial Instruments—The carrying amounts of the Company's financial instruments, including cash, receivables, accounts payable, and accrued liabilities approximate their fair values due to their short-term nature. The outstanding balance owed under the line of credit approximates its fair value due to the instrument's variable interest rate feature. Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of trade accounts receivable. The Company establishes reserves for estimated uncollectible accounts and believes its reserves are adequate.

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

Stock-Based Compensation—Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option award. The total number of stock options expected to vest is adjusted by estimated forfeiture rates. The Company determined the estimated fair value of each stock option on the date of grant using the Black-Scholes option valuation model. Compensation expense for restricted stock ("stock awards") is measured at the grant date and recognized ratably over the vesting period. The fair value of stock awards is determined based on the closing market price of the Company's common stock on the grant date.

Computation of Earnings (Loss) Per Share—Diluted net income per share is reported based on the more dilutive of the treasury stock or the two-class method. Under the two-class method, net income is allocated to common stock and participating securities. The Company's unvested restricted stock awards and certain unvested restricted stock units meet the definition of participating securities. Basic net income per share under the two-class method is computed by dividing net income adjusted for earnings allocated to unvested stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net income per share under the two-class method is computed by dividing net income adjusted for earnings allocated to unvested stockholders for the period by the weighted average number of common and common equivalent shares outstanding during the period. The Company excludes stock options from the calculation of diluted net income per share when the combined exercise price, unrecognized stock-based compensation and assumed tax benefits upon exercise are greater than the average market price for the Company's common stock because their effect is anti-dilutive. Stock options totaling 1.1 million and 1.8 million for the years ended December 31, 2012 and 2011, respectively were not included in the computation of diluted earnings per share as their effect was anti-dilutive. For the year ended December 31, 2010 there were no differences between the number of common shares used for the basic and diluted loss per share computations as the Company incurred a net loss. Due to the fact that the holders of participating securities are not contractually required to share in the Company's losses, in applying the two-class method to compute basic net loss per common share, no allocation to participating securities was made for periods in which the Company incurred a net loss.

Note 1. Company Operations and Summary of Significant Accounting Policies (Continued)

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2012 and 2011 (in thousands, except per share amounts):

	2012	2011
Basic net income per share:		
Net income	$ 4,993	$ 7,633
Less: income allocated to participating securities	(28)	(68)
Net income allocated to common stockholders	$ 4,965	$ 7,565
Weighted average common shares outstanding — basic	33,068	32,903
Net income per share — basic	$ 0.15	$ 0.23
Diluted net income per share:		
Net income	$ 4,993	$ 7,633
Less: income allocated to participating securities	(27)	(67)
Net income allocated to common stockholders	$ 4,966	$ 7,566
Weighted average common shares outstanding — basic	33,068	32,903
Dilutive securities	634	417
Weighted average common shares outstanding — diluted	33,702	33,320
Net income per share — diluted	$ 0.15	$ 0.23

Comprehensive Income (Loss) —Comprehensive income (loss) includes unrealized gains and losses excluded from the Company's Consolidated Statements of Operations. The component of accumulated other comprehensive loss for the year ended December 31, 2010 is an unrealized loss on marketable securities.

Restructuring Charges— In March 2009, the Company announced and implemented a restructuring plan (the "Restructuring Plan"). The Restructuring Plan primarily consisted of a workforce reduction (approximately 10% of the Company's total workforce) as well as consolidation of facility space at its Santa Clara, California location. The completion date for the workforce reduction was the end of the second quarter of fiscal year 2010, at which time the COBRA benefits expired for terminated employees. The expected completion date relating to the Santa Clara lease liability is November 2014, the end of the current lease term. The Company recorded a charge of $2.0 million during the year ended December 31, 2009, which is net of a $0.2 million stock-based compensation expense reversal for certain terminated employees. As of December 31, 2012 and 2011 $0.3 million and $0.2 million, respectively, is included in other current liabilities, and $0.2 million and $0.3 million respectively, is included in other non-current liabilities in the accompanying Consolidated Balance Sheets.

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

Accounting Periods—Each of the Company's fiscal quarters end on the Sunday closest to the end of the calendar quarter. The Company's fiscal year end is December 30, 2012. For ease of reference, the calendar quarter end dates are used herein.

Note 1. Company Operations and Summary of Significant Accounting Policies (Continued)

Recent Accounting Pronouncements—In July 2012, the FASB issued ASU No. 2012-02, *Intangibles—Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*, ("ASU 2012-02"), to simplify the testing for a drop in value of intangible assets such as trademarks, patents, and distribution rights. The amended standard reduces the cost of accounting for indefinite-lived intangible assets, especially in cases where the likelihood of impairment is low. The changes permit businesses and other organizations to first use subjective criteria to determine if an intangible asset has lost value. The amendments to U.S. GAAP will be effective for fiscal years starting after September 15, 2012. Early adoption is permitted. The Company is currently evaluating the impact of the pending adoption of ASU 2012-02 on the consolidated financial statements.

Note 2. Line of Credit

On August 10, 2012, the Company entered into an amended and restated $140.0 million senior secured syndicated credit facility (the "Senior Credit Facility"), which matures on August 10, 2017. The Senior Credit Facility amends and restates the Company's $120.0 million senior secured credit facility dated October 8, 2008. As part of this amendment, the Company incurred $1.0 million in deferred financing costs related to the Senior Credit Facility in addition to the $0.6 million it had previously recorded related to the original credit facility. Deferred financing costs are amortized on a straight line basis over the term of the Senior Credit Facility. As of December 31, 2012 and 2011, the Company had deferred financing costs of $1.5 million and $1.0 million, respectively, included as a portion of other non-current assets. The Senior Credit Facility bears interest at either the London Interbank Offered Rate ("LIBOR") or the base rate, plus, in each case, the applicable margin. The base rate is equal to the highest of (i) the lender's prime rate, (ii) the federal funds rate plus one-half of one percent and (iii) LIBOR plus one percent. The applicable margin is generally determined in accordance with a performance pricing grid based on the Company's leverage ratio and ranges from 1.25% to 2.50% for LIBOR rate loans and from 0.25% to 1.50% for base rate loans (weighted average interest rate of 1.46% at December 31, 2012). The agreement governing the Senior Credit Facility is subject to certain customary limitations, 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. The Company is also subject to financial covenants which include a funded debt to adjusted EBITDA ratio (as defined in the Senior Credit Facility, with adjusted EBITDA generally calculated as earnings before, among other adjustments, interest, taxes, depreciation, amortization, and stock-based compensation) not to exceed 3:1 as of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:1 as of the end of each fiscal quarter. The Senior Credit Facility is secured by substantially all present and future assets and properties of the Company.

As of December 31, 2012, the Company had $110.4 million available under the Senior Credit Facility. The Company's ability to borrow under the Senior Credit Facility fluctuates from time to time due to, among other factors, the Company's borrowings under the facility and its funded debt to adjusted EBITDA ratio. As of December 31, 2012 and 2011, the Company had $5.0 million and $42.0 million, respectively, outstanding under the Senior Credit Facility. As of December 31, 2012 and 2011, the Company was in compliance with all financial covenants.

Note 3. Income Taxes

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

	December 31,		
	2012	2011	2010
Current:			
Federal	$1,870	$2,494	$(6,976)
State	377	155	159
Total current provision (benefit)	2,247	2,649	(6,817)
Deferred:			
Federal	811	1,422	1,622
State	(440)	(220)	(954)
Total deferred provision	371	1,202	668
Provision (benefit) for income taxes	$2,618	$3,851	$(6,149)

The Company's income (loss) before provision (benefit) for income taxes was not subject to taxes in any jurisdictions outside of the United States.

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2012 and 2011 are shown below (in thousands).

	December 31,	
	2012	2011
Deferred tax assets:		
Net operating loss carryforwards	$917	$4,934
Acquired intangibles	3,933	4,284
Sale-leaseback, net	1,720	2,053
Capitalized research and development costs	579	1,330
Allowance for returns and discounts	2,800	1,619
Stock compensation	6,298	5,406
Tax credit carryforwards	1,520	1,636
Other, net	3,271	2,889
Total deferred tax assets	21,038	24,151
Deferred tax liabilities:		
Acquired intangibles	(13,811)	(16,577)
Depreciation	(3,954)	(3,933)
Total deferred tax liabilities	(17,765)	(20,510)
Net deferred tax assets and liabilities	$3,273	$3,641

The Company will continue to assess the realization of its deferred tax assets. Should the Company determine that it would not be able to realize all or part of its other components of the deferred tax asset in the future, an adjustment to the deferred tax asset would be charged to income in the period such determination were made. The Company is currently under Internal Revenue Service audit examination for the 2007 through 2010 tax years.

The Company recognizes excess tax benefits associated with the exercise of stock options directly to stockholders' equity only when realized. Accordingly, deferred tax assets are not recognized for net operating loss ("NOL") carryforwards resulting from excess tax benefits. As of December 31, 2012 and 2011, deferred tax assets do not include $1.1 million and $2.3 million, respectively of these excess tax benefits from employee stock option exercises that are a component of the Company's NOL carryforwards. Additional paid-in capital will be increased up to an additional $1.1 million if such excess tax benefits are realized.

Note 3. Income Taxes (Continued)

As of December 31, 2012, the Company had federal NOL carryforwards of approximately $3.0 million which will expire at various dates through December 31, 2031, unless previously utilized. The Company has federal research credits of $0.5 million which will expire at various dates through December 31, 2031, unless previously utilized. The Company has gross state research credits of $5.2 million which do not expire.

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

	Year ended December 31,		
	2012	2011	2010
Tax expense (benefit) at statutory tax rate	$2,664	$4,019	$(6,095)
State taxes (benefit), net of federal tax (benefit)	239	388	(734)
Permanent differences	26	159	1,173
Federal and state research credits—current year	(370)	(904)	(952)
(Benefit) liability for uncertain tax positions	(106)	204	74
Impact of change in federal and state tax rate on revaluing deferred tax assets	75	39	548
Other	90	(54)	(163)
	$2,618	$3,851	$(6,149)

The benefit of the federal 2012 research and development tax credit cannot be recognized until 2013, as the result of legislative approval occurring in January, 2013.

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

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

	2012	2011	2010
Beginning balance	$8,567	$8,085	$6,983
Increases related to prior year tax positions	372	—	346
Increases related to current year tax positions	366	566	623
Increases related to DHI pre-acquisition items	—	—	319
Decreases due to settlements	—	—	(92)
Expiration of the statute of limitations for the assessment of taxes	(254)	—	—
Other	—	(84)	(94)
Ending balance	$9,051	$8,567	$8,085

Included in the unrecognized tax benefits of $9.1 million at December 31, 2012 was $7.2 million of tax benefits that, if recognized, would reduce the Company's annual effective tax rate. We do not expect the Company's unrealized tax benefits to decrease over the next 12 months. Included in the unrecognized tax benefits of $8.6 million at December 31, 2011 was $6.9 million of tax benefits that, if recognized, would reduce the Company's annual effective tax rate. Included in the unrecognized tax benefits of $8.1 million at December 31, 2010 was $6.5 million of tax benefits that, if recognized, would reduce the Company's annual effective tax rate. The Company's policy is to recognize the interest expense and penalties related to income tax matters as a component of income tax expense. The Company has accrued approximately $0.7 million of interest and penalties associated with uncertain tax positions as of December 31, 2012.

Note 3. Income Taxes (Continued)

The Company is subject to periodic audits by domestic tax authorities. The Company's federal tax years for 1996 and forward are subject to examination by the U.S. authorities due to the carry forward of unutilized net operating losses and research and development credits. With few exceptions, the Company's tax years 2000 and forward are subject to examination by state and foreign tax authorities. The Company believes it has appropriate support for the income tax positions taken on its tax returns and that its accruals for tax liabilities are adequate for all open years based on an assessment of many factors, including past experience and interpretations of tax law applied to the facts of each matter.

Note 4. Stockholders' Equity

Preferred Stock. The Company's certificate of incorporation, as amended, authorizes the issuance of up to five million preferred shares. The Board of Directors is authorized to fix the number of shares of any series of preferred stock and to determine the designation of such shares. However, the amended certificate of incorporation specifies the initial series and the rights of that series. No shares of preferred stock were outstanding as of December 31, 2012 and 2011.

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

For the year ended December 31, 2012, the Company granted approximately 0.1 million shares of restricted stock awards and units to officers and management, which either have a time-based four-year vesting provision or performance-based vesting provisions. For the year ended December 31, 2011, the Company granted approximately 0.2 million shares of restricted stock awards and units to officers and management, which either have a time-based four-year vesting provision or performance-based vesting provisions. For the year ended December 31, 2010, the Company granted approximately 0.2 million shares of restricted stock awards to officers and management, all of which vest over a four-year period. A portion of the restricted stock granted in 2012 and 2011 was performance-based and vesting is tied to achievement of specific Company goals in 2014 and 2013, respectively. For purposes of measuring compensation expense, the amount of shares ultimately expected to vest is estimated at each reporting date based on management's expectations regarding the relevant performance criteria. The recognition of compensation expense associated with performance-based restricted stock requires judgment in assessing the probability of meeting the performance goals, as well as defined criteria for assessing achievement of the performance-related goals. The grant date of the performance-based restricted stock takes place when the grant is authorized and the specific achievement goals are communicated. The communication date of the performance goals can impact the valuation and associated expense of the restricted stock.

During the years ended December 31, 2012, 2011 and 2010, restricted stock units were granted to certain members of the Board of Directors in lieu of cash compensation as a part of the Company's non-employee director's deferred compensation program. The compensation expense associated with these grants of restricted stock units was $0.5 million, $0.4 million and $0.2 million for the years ended December 31, 2012, 2011 and 2010, respectively.

Equity Incentive Plan. The Company grants options and other stock based awards to employees and non-employee directors under its 2010 Equity Incentive Plan (the "2010 Plan") and previously granted options under the Amended and Restated 2001 Equity Incentive Plan, the 1998 Stock Incentive Plan and the 1996 Non-Employee Directors Stock Option Plan. The 2001, 1998 and 1996 Plans were terminated at the time of adoption of the 2010 Plan, but the terminated Plans continue to govern outstanding options granted thereunder. The Company has stock options and other stock based awards outstanding, which were issued under each of these equity incentive plans to certain employees and directors. Stock options granted under the various plans have terms ranging up to ten years, have exercise prices ranging from $3.19 to $19.48, and generally vest over four years. As of December 31, 2012, approximately 0.7 million shares remained available for grant under the 2010 Plan.

Note 4. Stockholders' Equity (Continued)

Employee Deferred Bonus Compensation Program. For the year ended December 31, 2012 and 2011, certain employees of the Company were eligible to participate in the Company's deferred bonus compensation program with respect to any payments received under the Company's cash incentive plan. Participating employees could elect to receive 50% or 100% of the cash value of their cash bonus in the form of fully vested, restricted stock units plus an additional premium as additional restricted stock units, issued under the 2010 Plan. The premium restricted stock units are subject to a one-year vesting requirement from the date of issuance.

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

Employee Stock Purchase Plan. Under the Company's 1983 Employee Stock Purchase Plan (the "ESPP"), full-time employees are allowed to purchase common stock through payroll deductions (which cannot exceed 10% of the employee's compensation) at the lower of 85% of fair market value at the beginning or end of each six-month purchase period. As of December 31, 2012, 1,009,505 shares had been sold under the Plan, leaving 250,410 shares available for future issuance.

Share Repurchase Program. On November 28, 2011, the Company announced that its Board of Directors authorized it to repurchase up to an aggregate of $25.0 million in shares of its common stock under the stock repurchase program. Any shares of common stock repurchased under this program will no longer be deemed outstanding upon repurchase and will be returned to the pool of authorized shares. At December 31, 2012, approximately $22.1 million remains available under this plan. This repurchase program will expire on November 8, 2013 unless extended by the Board of Directors.

Shares Reserved for Future Issuance. At December 31, 2012, approximately 4.7 million shares of common stock were reserved under the Company's equity incentive plans, and 250,410 were reserved for purchases under the ESPP.

Stock Offering. In January 2011, the Company completed a public offering of 4.6 million shares of its common stock at $13.15 per share. The Company received proceeds, net of underwriting discounts and commissions, of $57.9 million ($12.43 per share) and incurred approximately $0.7 million in related offering expenses. The Company has and expects to continue to use the net proceeds of this offering for working capital and other general corporate purposes, which may potentially include the acquisition or development of new technology, the acquisition of diagnostic or related companies, products or businesses or the repayment of existing indebtedness.

Note 5. Stock-Based Compensation

Compensation expense related to the Company's share-based awards for the years ended December 31, 2012, 2011 and 2010 was $6.6 million, $7.5 million and $5.2 million, respectively, of which $3.8 million, $4.6 million and $4.0 million, respectively, related to stock options and $2.8 million, $2.9 million and $1.2 million, respectively, related to restricted stock ("stock awards"). For the year ended December 31, 2012, 2011, and 2010 the Company recorded $0.6 million, $0.9 million and $- in stock-based compensation expense, respectively, associated with the deferred bonus compensation program, described in Note 4, of which $0.5 million, $0.9 million and $-, respectively, was initially recorded as a component of accrued payroll and related expenses.

Note 5. Stock-Based Compensation (Continued)

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

	Year ended December 31,		
	2012	2011	2010
Cost of sales	$0.6	$0.6	$0.6
Research and development	1.1	1.0	0.6
Sales and marketing	0.6	0.5	0.4
General and administrative	4.3	5.4	3.6
	$6.6	$7.5	$5.2

Compensation expense capitalized to inventory and compensation expense related to the Company's ESPP were not material for the year ended December 31, 2012, 2011 and 2010.

Stock Options

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

	Year ended December 31,		
	2012	2011	2010
Risk-free interest rate	0.83%	1.87%	2.40%
Expected option life (in years)	5.52	5.23	4.89
Volatility rate	0.46	0.47	0.52
Dividend rate	0%	0%	0%

The computation of the expected option life is based on a weighted-average calculation combining the average life of options that have already been exercised and post-vest cancellations with the estimated life of the remaining vested and unexercised options. The expected volatility is based on the historical volatility of the Company's stock. The risk-free interest rate is based on the U.S Treasury yield curve over the expected term of the option. The Company has never paid any cash dividends on its common stock, and does not anticipate paying any cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield of zero in the Black-Scholes option valuation model. The Company's estimated forfeiture rate is based on its historical experience and future expectations.

The Company's determination of fair value is affected by the Company's stock price as well as a number of assumptions that require judgment. The weighted-average fair value per share was $6.51, $5.92 and $6.86 for options granted during the years ended December 31, 2012, 2011 and 2010, respectively. The total intrinsic value was $2.0 million, $1.2 million and $0.8 million for options exercised during the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012, total unrecognized compensation expense related to stock options was approximately $4.2 million and the related weighted-average period over which it is expected to be recognized is approximately 2.0 years. The maximum contractual term of the Company's stock options is ten years.

Note 5. Stock-Based Compensation (Continued)

A summary of the status of stock option activity for the years ended December 31, 2010, 2011 and 2012 is as follows (in thousands, except price data and years):

	Number of Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at January 1, 2010	2,825	$11.41		
Granted	609	14.67		
Exercised	(122)	6.77		
Cancelled	(146)	10.72		
Outstanding at December 31, 2010	3,166	12.25		
Granted	617	13.61		
Exercised	(151)	7.93		
Cancelled	(215)	13.56		
Outstanding at December 31, 2011	3,417	12.60		
Granted	624	15.23		
Exercised	(351)	11.85		
Cancelled	(90)	11.94		
Outstanding at December 31, 2012	3,600	$13.15	6.85	$19,171
Vested and expected to vest at December 31, 2012	3,388	$13.05	6.73	$18,362
Exercisable at December 31, 2012	1,968	$12.55	5.82	$11,650
Available for future grant at December 31, 2012	702			

Stock Awards

The fair value of stock awards is determined based on the closing market price of the Company's common stock on the grant date. The Company grants both time-based and performance-based stock awards. Compensation expense for time-based stock awards is measured at the grant date and recognized ratably over the vesting period. A portion of the stock awards granted in 2012 and 2011 was performance-based and vesting is tied to achievement of specific Company goals in 2014 and 2013, respectively. For purposes of measuring compensation expense, the amount of shares ultimately expected to vest is estimated at each reporting date based on management's expectations regarding the relevant performance criteria. The recognition of compensation expense associated with performance-based stock award requires judgment in assessing the probability of meeting the performance goals, as well as defined criteria for assessing achievement of the performance-related goals. The grant date of the performance-based stock award takes place when the grant is authorized and the specific achievement goals are communicated. The communication date of the performance goals can impact the valuation and associated expense of the stock award.

Note 5. Stock-Based Compensation (Continued)

A summary of the status of stock awards activity for the years ended December 31, 2010, 2011 and 2012 is as follows (in thousands, except price data):

	Shares	Weighted-Average Grant Date Fair Value
Non-vested at January 1, 2010	218	$11.58
Granted	248	14.12
Vested	(99)	12.85
Forfeited	(16)	11.02
Non-vested at December 31, 2010	351	14.02
Granted	235	13.70
Vested	(39)	15.22
Forfeited	(45)	13.29
Non-vested at December 31, 2011	502	13.65
Granted	145	15.69
Vested	(107)	15.29
Forfeited	(18)	13.81
Non-vested at December 31, 2012	522	$13.87

In 2012, the Company issued approximately 0.1 million restricted share units in exchange for the 2011 deferred bonus liability of $0.9 million.

The total amount of unrecognized compensation expense related to non-vested stock awards as of December 31, 2012 was approximately $2.2 million, which is expected to be recognized over a weighted-average period of approximately 1.6 years.

Note 6. Commitments and Contingencies

Leases

The Company leases its facilities and certain equipment. Commitments for minimum rentals under non-cancelable leases at the end of 2012 are as follows (in thousands):

Years ending December 31,	Operating Leases	Lease Obligation
2013	$1,747	$1,117
2014	1,494	1,125
2015	702	1,134
2016	725	1,145
2017	249	1,152
Thereafter	-	3,351
Total minimum lease payments	$4,917	9,024
Less amount representing interest		(3,077)
Present value of lease obligation		5,947
Less current portion		(380)
Long-term lease obligation		$5,567

Note 6. Commitments and Contingencies (Continued)

Rent expense under operating leases totaled approximately $2.0 million for the year ended December 31, 2012, $1.8 million for the year ended December 31, 2011 and $1.8 million for the year ended December 31, 2010. In the fourth quarter of 2011, the Company entered into a new operating lease to rent approximately 11,000 square feet of additional office space in San Diego with a lease term through October 2013. The operating lease at the Company's Santa Clara location has a lease term through November 2014. In the fourth quarter of 2011, the Company exercised its renewal option at the Athens, Ohio location, thereby extending the lease term to 2017 with options to extend the lease for two additional five-year periods.

During 1999, the Company completed a sale and leaseback transaction of its San Diego facility. The facility was sold for $15.0 million, of which $3.8 million was capital contributed by the Company. The sale was an all cash transaction, netting the Company approximately $7.0 million. The Company is a 25% limited partner in the partnership that acquired the facility. The transaction was deemed a financing transaction under the guidance in ASC Topic 840-40, Accounting for Sales of Real Estate. The assets sold remain on the books of the Company and will continue to be depreciated over the estimated useful life. In December 2009, the Company amended the terms of its lease agreement which had no significant impact on the Company's financial statements. The amended terms include a new ten-year lease term through December 2019, with options to extend the lease for up to three additional five-year periods. The Company will amortize the lease obligation over this new term. The amount of the monthly rental payments remain the same under the amendment. In addition, the Company has the option to purchase the general partner's interest in the partnership in January 2015 for a fixed price. The Company has determined that the partnership is a variable interest entity (VIE). The Company is not, however, the primary beneficiary of the VIE as it does not absorb the majority of the partnership's expected losses or receive a majority of the partnership's residual returns. The Company made lease payments to the partnership of approximately $1.1 million for each of the three years ended December 31, 2012, 2011 and 2010.

Purchase Commitments

The Company has $4.7 million in firm purchase commitments with respect to planned capital expenditures as of December 31, 2012.

Legal

The Company is involved in various claims and litigation matters from time to time in the ordinary course of business. Management believes that all such current legal actions, in the aggregate, will not have a material adverse effect on the Company. The Company also maintains insurance, including coverage for product liability claims, in amounts which management believes are appropriate given the nature of its business. At December 31, 2012 and 2011, the Company had $0.3 million and $0.8 million, respectively, accrued as a liability for various legal matters where the Company deemed the liability probable and estimable.

Licensing Arrangements

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

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

Note 6. Commitments and Contingencies (Continued)

In conjunction with Financial Accounting Standards Board Accounting Standard Update No. 2009-05, *Fair Value Measurements and Disclosures (Topic 820),* the Company assigned $28.8 million to the licensed technology and $0.7 million as a one-time charge to cost of sales to settle royalty claims. In determining the fair value allocation between the intangible asset licensed technology and the one-time charge to cost of sales, the Company assessed the past and estimated future revenue streams related to present and future products that use the patents that are subject to the Amendment. The effective life and related amortization of the licensed technology will be based on the higher of the percentage of usage or the straight-line method. This percentage of usage will be determined using the revenues generated from products covered by the patents that are subject to the Amendment. The terms of the Amendment provide for an estimated useful life of 3.5 years for this asset. The Company recorded $8.0 million and $4.0 million of amortization expense in 2012 and 2011, respectively, included as a portion of cost of sales. Prior to the buy-out, the Company recorded $4.9 million and $6.0 million of royalty expense in 2011 and 2010, respectively.

In addition to the royalty agreement noted above, the Company has entered into various other licensing and royalty agreements, which largely require payments based on specified product sales as well as the achievement of specified milestones. The Company had royalty and license expenses relating to those agreements of approximately $1.4 million, $1.9 million and $1.8 million for the years ended December 31, 2012, 2011 and 2010, respectively.

Research and Development Agreements

The Company has entered into various research and development agreements which provide it with rights to develop, manufacture and market products using the intellectual property and technology of its collaborative partners. Under the terms of certain of these agreements, the Company is required to make periodic payments based on achievement of certain milestones or resource expenditures. These milestones generally include achievement of prototype assays, validation lots and clinical trials. At December 31, 2012, total current commitments due under the terms of these agreements are estimated at $2.1 million in the aggregate. The commitments will fluctuate as we agree to new phases of development under the existing arrangements.

Note 7. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented 14%, 14%, and 15% of total revenue for the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012 and 2011, balances due from foreign customers, in U.S. dollars, were $2.8 million and $4.8 million, respectively.

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

	Year ended December 31,		
	2012	2011	2010
Customer:			
A	16%	15%	12%
B	18%	17%	12%
	34%	32%	24%

As of December 31, 2012 and 2011, accounts receivable from individual customers with balances due in excess of 10% of total accounts receivable totaled $22.4 million and $5.5 million, respectively.

Note 7. Industry and Geographic Information (Continued)

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

	Long-lived assets December 31,		Total revenue year ended December 31,		
	2012	2011	2012	2011	2010
United States operations					
Domestic	$34,156	$28,434	$134,239	$137,096	$95,964
Foreign	—	—	21,502	21,507	17,375
Total	$34,156	$28,434	$155,741	$158,603	$113,339

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

	Year ended December 31,		
	2012(1)	2011(1)	2010(1)
Infectious disease	$110,982	$112,227	$68,869
Women's health	32,653	32,715	32,246
Gastrointestinal disease	6,328	6,920	5,967
Other	3,326	4,323	3,864
	$153,289	$156,185	$110,946

(1) Consolidated net product revenues disclosed above excludes royalty, license and grant revenue of $2.5 million, $2.4 million and $2.4 million for the years ended December 31, 2012, 2011 and 2010, respectively, as this revenue is not associated with the direct sale of a product by the Company.

Note 8. Fair Value Measurement

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

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

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

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

As of December 31, 2012 and 2011, the carrying amount of the Company's Senior Credit Facility approximates fair value because it has a variable interest rate that reflects market changes to interest rates and changes in the Company's leverage ratio. As of December 31, 2012 and 2011, the Company used Level 2 inputs to determine the fair value of its Senior Credit Facility. As of December 31, 2012 and 2011, the carrying amount of the Company's cash equivalents approximates fair value. Cash equivalents primarily consisted of funds held in a money market account. As of December 31, 2012 and 2011, the carrying value of cash equivalents was $11.0 million and $47.0 million, respectively, and was determined based on Level 1 inputs.

Note 9. Employee Benefit Plan

The Company has a defined contribution 401(k) plan (the "401(k) Plan") covering all employees who are eligible to join the 401(k) Plan upon employment. Employee contributions are subject to a maximum limit by federal law. This Plan includes an employer match of 50% on the first 6% of pay contributed by the employee. The Company contributed approximately $0.8 million, $0.8 million and $0.7 million to the 401(k) Plan during the year ended December 31, 2012, 2011 and 2010, respectively.

Note 10. Acquisition

On February 19, 2010, the Company acquired DHI a privately-held, IVD company, based in Athens, Ohio, that manufactures FDA-cleared direct and culture-based fluorescent IVD assays used in hospital and reference laboratories for a variety of diseases, including viral respiratory infections, herpes, Chlamydia and other viral infections, and thyroid diseases. DHI's direct sales force serves North American customers, and its products are sold via distributors outside the United States. DHI's products are offered under various brand names including, among others, ELVIS®, R-Mix™, Mixed Fresh Cells™, FreshCells™, ReadyCells™ and Thyretain™. The Company paid approximately $131.2 million in cash to acquire DHI. The Company paid for the acquisition of DHI using cash and cash equivalents on hand and borrowed $75.0 million under the Senior Credit Facility. Included in the Consolidated Statements of Operations for the year ended December 31, 2010 is revenue and net income of $34.7 million and $0.4 million, respectively, related to the operations of DHI since the acquisition. Net income of $0.4 million includes the amortization of acquired intangibles and interest expense on the borrowing under the Company's Senior Credit Facility.

The purchase price of DHI is allocated to the underlying net assets acquired and liabilities assumed based on their respective fair values as of February 19, 2010 with any excess purchase price allocated to goodwill. The Company's allocation of the purchase price to the net tangible and intangible assets acquired and liabilities assumed as of December 31, 2010 was as follows:

(in thousands)		
Total cash consideration	$	131,212
Allocated to:		
Current assets		27,162
Property, plant and equipment		7,799
Other non-current assets		82
In-process research and development		2,110
Intangible assets		53,410
Current liabilities (excluding current portion of note payable)		(4,169)
Note payable to state agency		(1,882)
Other non-current liabilities		(17,843)
Goodwill		64,543
Net assets acquired	$	131,212

Included in the goodwill amount is $16.8 million related to deferred tax liabilities recorded as a result of the inability to deduct intangible amortization expense associated with the acquisition of DHI. The Company's cost basis in the intangible assets is zero requiring an adjustment to the deferred tax liability to properly capture the Company's ongoing tax rate. The remainder of the goodwill balance reflects the complementary strategic fit that the acquisition of DHI brought to the Company.

The change in goodwill during the year ended December 31, 2010 was as follows:

(in thousands)		
Balance at December 31, 2009	$	6,470
Additions recorded in connection with acquisition of DHI		64,543
Balance at December 31, 2010	$	71,013

Note 10. Acquisition (Continued)

The following table presents the amounts assigned to the identifiable intangible assets acquired. Intangible assets (except for in-process research and development) are amortized over the weighted-average amortization periods noted below for each type. In-process research and development is not amortized, but assessed at least annually for impairment, or more frequently when events or changes in circumstances indicate that the asset might be impaired.

(in thousands)	Fair value	Weighted-average amortization period (years)
Purchased technology	$ 46,570	8.0
Customer relationships	5,450	8.0
In-process research and development	2,110	N/A
Patents and trademarks	1,390	15.0
Total	$ 55,520	

In-process research and development primarily relates to the future commercialization of DHI's reader instrument to be used with DHI's existing and future DFA and culture-based tests. The projected cash flows utilized in the Company's valuation of the fair value of the in-process research and development acquired were based on key assumptions such as estimates of revenue and operating profits related to the in-process research and development considering its stage of development; the time and resources needed to complete the development and approval of the related product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential alternative treatments in any future target markets.

The following unaudited pro forma financial information shows the combined results of operations of the Company, including DHI, as if the acquisition had occurred as of the beginning of the periods presented. The unaudited pro forma financial information is not intended to represent or be indicative of the Company's consolidated financial results of operations that would have been reported had the acquisition been completed as of the beginning of the periods presented and should not be taken as indicative of the Company's future consolidated results of operations.

(in thousands, except per share data)	Year ended December 31, 2010
Pro forma total revenues	$ 119,044
Pro forma net (loss) income	$ (13,989)
Pro forma basic net (loss) earnings per share(1)	$ (0.49)
Pro forma diluted net (loss) earnings per share(1)	$ (0.49)

(1) Included in the pro forma $0.49 net loss per share for the year ended December 31, 2010 is $5.3 million of transaction expenses relating to the acquisition of DHI, which contributed $0.11 to the pro forma net loss per share.

Note 11. Selected Quarterly Financial Data (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
2012				
Total revenues	$37,960	$30,858	$32,998	$53,925
Cost of sales (excludes amortization of intangible assets)	14,808	14,008	14,872	17,597
Gross profit (1)	21,714	15,412	16,688	34,890
Total costs and expenses	37,490	35,377	34,220	39,808
Net income (loss)	51	(3,122)	(676)	8,740
Basic and diluted net earnings (loss) per share (3)	0.00	(0.09)	(0.02)	0.26
2011				
Total revenues	$59,595	$27,509	$33,108	$38,391
Cost of sales (excludes amortization of intangible assets)	20,043	12,540	14,996	15,286
Gross profit (2)	37,882	13,299	16,442	21,448
Total costs and expenses	41,647	32,612	34,352	36,252
Net loss	11,448	(3,660)	(1,113)	958
Basic and diluted net loss per share (3)	0.35	(0.11)	(0.03)	0.03

(1) Included in 2012 quarterly gross profit is amortization of intangible assets of $1.4 million for each quarter.

(2) Included in 2011 quarterly gross profit is amortization of intangible assets of $1.7 million for each quarter.

(3) Due to the computation of earnings (loss) per share, the sum of the quarterly amounts may not equal the full-year results.

SCHEDULE II

QUIDEL CORPORATION

CONSOLIDATED VALUATION AND QUALIFYING ACCOUNTS

(in thousands)

Description	Balance at beginning of period	Additions: Charges to costs and expenses(1)	Additions: Charges to other accounts	Deductions(2)	Balance at end of period
Year ended December 31, 2012:					
Accounts receivable allowance	$1,960	$10,849	$—	$7,854	$4,955
Year ended December 31, 2011:					
Accounts receivable allowance	$1,882	$7,909	$—	$7,831	$1,960
Year ended December 31, 2010:					
Accounts receivable allowance	$3,337	$4,461	$—	$5,916	$1,882

(1) Represents charges associated primarily to accruals for early payment discounts, contract rebates and bad debt.

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

EXHIBIT INDEX

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of January 10, 2010, by and among Quidel Corporation, Fairway Acquisition Corporation, Diagnostic Hybrids, Inc., and David R. Scholl, Ph.D., in his capacity as securityholder agent. (Incorporated by reference to Exhibit 2.1 to the Registrant's Form 8-K filed on January 11, 2010.)
3.1	Restated Certificate of Incorporation of Quidel Corporation. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2010.)
3.2	Amended and Restated Bylaws of Quidel Corporation. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on May 21, 2012.)
4.1	Certificate of Designations of Series C Junior Participating Preferred Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2010.)
4.2	Specimen stock certification. (Incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-3 filed on August 31, 2010.)
10.1(1)	Registrant's Amended and Restated 1983 Employee Stock Purchase Plan. (Incorporated by reference to Appendix B to the Registrant's Proxy Statement filed on April 6, 2012.)
10.2(1)	Registrant's 1990 Employee Stock Option Plan. (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1990.)
10.3(1)	Registrant's 1996 Non-Employee Directors Plan. (Incorporated by reference to Registrant's Proxy Statement filed on September 27, 1996.)
10.4(1)	Registrant's 1998 Stock Incentive Plan. (Incorporated by reference to Exhibit 10.7 to the Registrant's Form 10-Q for the quarter ended June 30, 2007.)
10.5(1)	Registrant's Amended and Restated 2001 Equity Incentive Plan, effective as of May 12, 2009. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 18, 2009.)
10.6(1)	Quidel Corporation Amended and Restated 2010 Equity Incentive Plan. (Incorporated by reference to Appendix A to the Registrant's Proxy Statement filed on April 6, 2012.)
10.7(1)	Form of Notice of Grant of Award and Award Agreement for Quidel Corporation 2010 Equity Incentive Plan. (Incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-8 filed on May 14, 2010.)
10.8(1)	Form of Restricted Stock Award Agreement for Quidel Corporation 2010 Equity Incentive Plan. (Incorporated by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-8 filed on May 14, 2010.)
10.9	Settlement Agreement effective April 1, 1997 between the Registrant and Becton, Dickinson and Company. (Incorporated by reference to Exhibit 10.18 to the Registrant's Form 10-K for the year ended March 31, 1997.)
10.10	Rosenstein License Agreement effective April 1, 1997 between the Registrant and Becton, Dickinson and Company. (Incorporated by reference to Exhibit 10.20 to the Registrant's Form 10-K for the year ended March 31, 1997.)
10.11	Settlement Agreement dated April 27, 2005 between the Registrant and Inverness Medical Innovations, Inc. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 3, 2005.)
10.12	Second Amendment to Quidel/Inverness Settlement Agreement dated September 27, 2011. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on September 28, 2011.)
10.13	Form of Single Tenant Absolute Net Lease. (Incorporated by reference to Exhibit 10.7 to the Registrant's Form 8-K filed on January 4, 2000.)
10.14	Second Amendment to Single Tenant Absolute Net Lease. (Incorporated by reference to Exhibit 10.1 to Registrant's Form 8-K filed on December 29, 2009.)

Exhibit Number	Description
10.15(1)	Form of Indemnification Agreement—Corporate Officer and/or Director. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on August 23, 2005.)
10.16(1)	Employment Agreement, dated as of January 16, 2009, between the Registrant and Douglas C. Bryant. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 20, 2009.)
10.17(1)	Stock Option Agreement, dated as of January 16, 2009, between the Registrant and Douglas C. Bryant. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on January 20, 2009.)
10.18(1)	Restricted Stock Agreement, dated as of January 16, 2009, between the Registrant and Douglas C. Bryant. (Incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed on January 20, 2009.)
10.19(1)	Agreement Re: Change in Control, dated as of January 16, 2009, between the Registrant and Douglas C. Bryant. (Incorporated by reference to Exhibit 10.4 to the Registrant's Form 8-K filed on January 20, 2009.)
10.20(1)	Employment Offer Letter, entered into on June 5, 2008, between the Registrant and Robert J. Bujarski. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on June 6, 2008.)
10.21(1)	Agreement Re: Change in Control, entered into on June 5, 2008, between the Registrant and Robert J. Bujarski. (Incorporated by reference to Exhibit 10.2 to Registrant's Form 8-K filed on June 6, 2008.)
10.22(1)	Randall Steward Employment Offer Letter, dated as of September 12, 2011. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on October 21, 2011.)
10.23(1)	Agreement Re: Change in Control, dated as of September 19, 2011, between the Registrant and Randall Steward. (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on October 21, 2011.)
10.24(1)	Employment Offer Letter, dated May 9, 2011, between the Registrant and Mark W. Smits. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended June 30, 2011.)
10.25(1)	Agreement Re: Change in Control, entered into on May 11, 2011, between the Registrant and Mark W. Smits. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-Q for the quarter ended June 30, 2011.)
10.26(1)	Agreement Re: Change in Control, entered into on June 25, 2007, between the Registrant and Scot M. McLeod. (Incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed on June 26, 2007.)
10.27(1)	Amendment of Agreement Re: Change in Control, dated December 31, 2007, between the Registrant and Scot M. McLeod. (Incorporated by reference to Exhibit 10.9 to the Registrant's Form 8-K filed on January 3, 2008.)
10.28(1)	Change in Control Agreement dated July 19, 2004 between the Registrant and Michael J. Beck. (Incorporated by reference to Exhibit 10.35 to the Registrant's Form 10-Q for the quarter ended June 30, 2004.)
10.29(1)	Amendment of Agreement Re: Change in Control, dated December 31, 2007, between the Registrant and Michael J. Beck. (Incorporated by reference to Exhibit 10.6 to the Registrant's Form 8-K filed on January 3, 2008.)
10.30(1)	Agreement Re: Change in Control, entered into on November 7, 2008, between the Registrant and John D. Tamerius, Ph.D. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on November 7, 2008.)
10.31(1)	Employment Offer Letter, dated June 22, 2009, between the Registrant and Timothy T. Stenzel. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2009.)
10.32(1)	Agreement Re: Change in Control, entered into on September 1, 2009, between the Registrant and Timothy T. Stenzel. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-Q for the quarter ended September 30, 2009.)
10.33(1)	Q4 2010 Employee Deferred Compensation Program for the Registrant. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on September 8, 2010.)
10.34(1)	2011 Employee Deferred Bonus Compensation Program for the Registrant. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on December 17, 2010.)

Exhibit Number	Description
10.35(1)	2011 Leadership Incentive Compensation Plan (Cash) for the Registrant. (Incorporated by reference to Exhibit 10.39 to the Registrant's Form 10-K for the year ended December 31, 2010.)
10.36(1)	2011 Equity Incentive Plan Grants to the Registrant's Executive Officers. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 7, 2011.)
10.37(1)	2011 Annual Base Salaries for the Registrant's Executive Officers, effective as of February 28, 2011. (Incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on March 7, 2011.)
10.38(1)	2012 Cash Incentive Compensation Plan (Incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on March 6, 2012)
10.39(1)	2012 Employee Deferred Bonus Compensation Program (Incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on March 6, 2012)
10.40(1)	2012 Equity Incentive Plan Grants to the Registrant's Executive Officers (Incorporated by reference to Exhibit 10.3 of the Registrant's Form 8-K filed on March 6, 2012)
10.41(1)	2012 Annual Base Salaries for the Registrant's Executive Officers, effective as of March 5, 2012 (Incorporated by reference to Exhibit 10.4 of the Registrant's Form 8-K filed on March 6, 2012)
10.42(1)	2011 Cash Bonus Awards (Incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on March 2, 2012)
10.43	Amended and Restated Credit Agreement, by and among the Registrant, as Borrower, each lender from time to time party thereto (collectively, "Lenders" and individually, a "Lender") and Bank of America, N.A. as Agent, Swing Line Lender and L/C Issuer, dated as of August 10, 2012. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on August 10, 2012.)
10.44	Amended and Restated Security Agreement by and among the Registrant, as Borrower, the material subsidiaries of Borrower, each additional grantor that may become a party thereto and Bank of America, N.A., as Agent, dated as of August 10, 2012. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on August 10, 2012.)
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification by Principal Executive Officer of the Registrant pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by Principal Financial and Accounting Officer of the Registrant pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications by Principal Executive Officer and Principal Financial and Accounting Officer of the Registrant pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101**	XBRL Instance Document
101**	XBRL Taxonomy Extension Schema Document
101**	XBRL Taxonomy Calculation Linkbase Document
101**	XBRL Taxonomy Extension Definition Linkbase Document
101**	XBRL Taxonomy Label Linkbase Document
101**	XBRL Taxonomy Presentation Linkbase Document

* Filed / furnished herewith

** Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the

submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.

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

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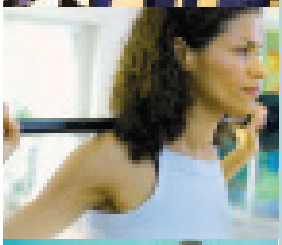

Life is a series of tests, some are just more important than others.

QUIDEL SENIOR MANAGEMENT

Douglas C. Bryant
President and Chief Executive Officer

Randall J. Steward
Chief Financial Officer

Timothy T. Stenzel, M.D., Ph.D.
Chief Scientific Officer

Robert J. Bujarski
SVP, Business Development and General Counsel

Mark W. Smits
SVP, Commercial Operations – North America

John D. Tamerius, Ph.D.
SVP, Clinical and Regulatory Affairs

BOARD OF DIRECTORS

Mark A. Pulido
Chairman of the Board
Quidel Corporation

Douglas C. Bryant
President and Chief Executive Officer
Quidel Corporation

Thomas D. Brown
Retired Senior Vice President and President of the Diagnostics Division of Abbott Laboratories

Rod F. Dammeyer
President
CAC, LLC

Mary Lake Polan M.D., Ph.D., M.P.H.
Professor and Chair Emeritus,
Department of Gynecology and Obstetrics
Stanford University School of Medicine

Jack W. Schuler
Co-Founder of Crabtree Partners, LLC

Kenneth F. Buechler, Ph.D.
Founder, Former President and
Chief Scientific Officer, Biosite Incorporated

ANNUAL MEETING

The annual meeting of shareholders will be held at 8:30 a.m., Tuesday, May 14, 2013, at:

San Diego Marriott Del Mar
11966 El Camino Real
San Diego, CA 92130

Outside Legal Counsel
Gibson, Dunn & Crutcher LLP
Irvine, California 92612

Snell & Wilmer, LLP
Phoenix, Arizona 85004

Independent Registered Public Accounting Firm
Ernst & Young LLP
San Diego, California 92101

Stockholder Inquiries
Inquiries related to stock transfer or lost certificates should be directed to the Transfer Agent.

Transfer Agent & Registrar
American Stock Transfer & Trust Company
59 Maiden Lane
Plaza Level,
New York, New York 10038
800.937.5449

Nasdaq Listing
Quidel common stock is traded on the Nasdaq Global Market under the symbol "QDEL."

Form 10-K and form 10-Q
A copy of the Company's Annual Report on form 10-K, Quarterly Reports on form 10-Q and other reports that we file with the Securities and Exchange Commission are available without charge upon request. Please contact Investor Relations.

Investor Relations
10165 McKellar Court
San Diego, California 92121 USA
858.552.7955
ir@quidel.com

Quidel's annual, quarterly, periodic reports, press releases and other information are located on Quidel's website: quidel.com

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QUIDEL

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Quidel, Northern California Operations
Santa Clara, California USA

Diagnostic Hybrids, A Quidel Company
Athens, Ohio USA

This annual report contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, seasonality, the timing of onset, length and severity of cold and flu seasons, the level of success in executing on our strategic initiatives, our reliance on sales of our influenza diagnostic tests, uncertainty surrounding the detection of novel influenza viruses involving human specimens, our ability to develop new products and technology, adverse changes in the competitive and economic conditions in domestic and international markets, our reliance on and actions of our major distributors, technological changes and uncertainty with research and technology development, including any molecular-based technology, the medical reimbursement system currently in place and future changes to that system, manufacturing and production delays or difficulties, adverse actions or delays in product reviews by the U.S. Food and Drug Administration ("FDA"), compliance with FDA, environmental and other regulations, our ability to meet unexpected increases in demand for our products, our ability to execute our strategy, including the integration of new companies or technologies, disruptions in the global capital and credit markets, our ability to hire key personnel, intellectual property, product liability, environmental or other litigation, potential required patent license fee payments not currently reflected in our costs, adverse changes in our international markets, potential inadequacy of booked reserves and possible impairment of goodwill, and lower-than-anticipated acceptance, sales or market penetration of our new products. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," and similar words, although some forward-looking statements are expressed differently. The risks described under "Risk Factors" in reports and registration statements that we file with the SEC from time to time should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this annual report. We undertake no obligation to publicly release any revision or update of these forward-looking statements, except as required by law.