QUIDEL CORP /DE/
Form 10-K
February 25, 2011

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2010

OR

o **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**	**92121**
(Address of principal executive offices)	(Zip Code)

858-552-1100

(Registrant s telephone number, including area code)

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

Title of each class	Name of each exchange on which registered
Common stock, $0.001 par value and accompanying purchase rights	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 o No þ

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 o No þ

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 þ No o

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 o No o

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. o

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

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o	Smaller reporting company o
		(Do not check if a 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 o No þ

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant was $297,685,332 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 22, 2011, 33,138,329 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 2011 Annual Meeting of Stockholders (to be held on May 10, 2011) are incorporated by reference into Part III, Items 10, 11, 12, 13 and 14 of this Annual Report on Form 10-K.

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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, 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 statement 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, effective tax rate and the effect the DHI acquisition will have on the seasonality of our business; 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 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.

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

diseases, bone health, thyroid diseases, and fecal occult blood. In February 2010, we expanded our operations through the acquisition of Diagnostic Hybrids, Inc., or DHI, a privately-held, in vitro diagnostics, or 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.

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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*.

Recent Developments

In January 2011, we completed a public offering of 4.6 million shares of our common stock at $13.15 per share. We received proceeds, net of underwriting discounts and commissions, of $57.9 million ($12.43 per share) and expect to incur approximately $0.7 million in related offering expenses. We expect 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.

Business Strategy

Our primary objective is to create shareholder value by building a broader-based diagnostic company, with products in market segments in which we have significant expertise and know-how.

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

lateral flow immunoassay tests;

direct fluorescent assays (DFA) and culture-based tests; and

molecular diagnostic tests.

Our strategy to accomplish our primary objective includes the following:

leveraging our current infrastructure to develop and launch new lateral flow and DFA products;

developing a molecular diagnostics franchise; and

strengthening our position with distribution partners to gain more emphasis on our products in the United States 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;

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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 of 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 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, or 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, 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, or CLIA.

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Products

We provide diagnostic testing solutions under various brand names, including, among others, the following: QuickVue®, QuickVue+®, Quidel®, MicroVue , FreshCells™ , D³ FastPoint™, Super E-Mix™, ELVIS® 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 a 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 HSV-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.

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

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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 (iFOB). Our QuickVue® iFOB 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 iFOB 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 D^3 IFA Enterovirus kit are used by reference laboratories and acute care hospitals.

Helicobacter pylori (H. pylori). H. pylori is the bacterium associated with approximately 80% of patients diagnosed with peptic ulcers in the U.S. *H. pylori* is implicated in chronic gastritis and is recognized by the World Health Organization as a Class 1 carcinogen that may increase a person s risk of developing stomach cancer. 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 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.

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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, 2010, 2009 and 2008, sales of our infectious disease products accounted for 61%, 78% and 72%, 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 $24.6 million, $12.5 million and $11.1 million for the years ended December 31, 2010, 2009 and 2008, respectively. DHI contributed $9.1 million to the total research and development expenses for the year ended December 31, 2010. 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 high quality results, are cost-effective to use, and improve patient outcomes as a result.

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 direct 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.

In contrast to the U.S. POC market and the use of waived or moderately complex tests, 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 use of 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 2010, we continued to invest in several key areas: further validation of customer needs through voice of customer studies (VOC), support for clinical research to highlight the usefulness and expanding our communications through extensive print and internet advertising, direct mail, promotional campaigns, public relations, peer-reviewed technical publications, professional shows and exhibits, symposia, medical education and support of health economics and outcomes research. Our VOC emphasis enables us to better understand customers needs and requirements in both

domestic and international markets in order to focus our product marketing and distribution partner plans. For example, annual post-

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season flu market research allows us to measure the success of our messaging and the effectiveness of various incentive programs to drive adoption as well as identify new product requirements and assess relevant customer trends for future application to the product line.

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 31%, 52% and 57% of our total revenue for the years ended December 31, 2010, 2009 and 2008, respectively. We had sales to one distributor for whom sales exceeded 10% of total revenue for the year ended December 31, 2010. This distributor was Cardinal Healthcare Corporation (Cardinal).

See Note 8. Industry and Geographic Information in the Notes to Consolidated Financial Statements included in this Annual Report.

Manufacturing

In 2010, we had manufacturing operations in San Diego and Santa Clara, California and Athens, Ohio. The San Diego facility, our largest manufacturing operation, produces our lateral flow, immunoassay products. The Santa Clara facility manufactures our microtiter plate 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 third party located in Southern California.

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.

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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 European Conformity (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 2027 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

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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 distribution agreements, we have agreed to indemnify the distributors 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. (formerly, Inverness Medical Innovations, Inc.) (ALR), Beckman Coulter Primary Care Diagnostics (Beckman), Fisher Scientific Corporation (Fisher), Sekisui Medical Co., LTD. (Sekisui), 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 molecular diagnostics in areas of infectious diseases in which we currently have relevant market share.

Human Resources

As of December 31, 2010, we had 532 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, 2010 are listed below, followed by a brief account of their business experience during the past five years or more. Officers are normally appointed annually by the Board of Directors at a meeting of the Board of Directors. 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. None of

these officers has been involved in any court or administrative proceeding within the past ten years adversely reflecting on the officer s ability or integrity.

Douglas C. Bryant, 53, 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.

John M. Radak, 50, became our Chief Financial Officer on February 1, 2007. Prior to joining us, Mr. Radak was Vice President of Finance and Chief Accounting Officer since January 2003 for Invitrogen Corporation, a leading provider of research tools for the life science industry. Mr. Radak also served as Vice President of Finance and Corporate Controller for Sunrise Medical Inc. from December 1994 to August 2001. Prior to joining Sunrise Medical Inc., Mr. Radak held a variety of senior financial management positions with manufacturing companies in the medical device and computer industries. After receiving his B.A. in Business Administration from California State University, Fullerton, Mr. Radak began his career with Deloitte Haskins and Sells. Mr. Radak holds an MBA from the University of Southern California and is a Certified Public Accountant (inactive).

Timothy T. Stenzel, M.D., Ph.D., 49, 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., 42, rejoined us as 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.

David R. Scholl, Ph.D., 55, has been our Senior Vice President, Commercial Operations and President of Diagnostic Hybrids since February 2010. Prior to joining us, Dr. Scholl was President, Chief Executive Officer and Chairman of the Board of Diagnostic Hybrids. Dr. Scholl joined Diagnostic Hybrids soon after its founding in 1983 as its Director of Research. Dr. Scholl was awarded a post-doctoral fellowship at the Roche Institute for Molecular Biology in Nutley, New Jersey from 1981 to 1983. Dr. Scholl received his Ph.D. from Ohio University and a B.A. in Biology from Indiana University, South Bend.

Scot M. McLeod, 46, 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 thirteen 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 manufacturing 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., 65, 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 Special 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

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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, 2010, total revenue decreased 31% to $113.3 million from $164.3 million for the year ended December 31, 2009. This was largely driven by a decrease in sales of our influenza products as a result of the influenza pandemic which occurred in 2009 which was partially offset by the acquisition of DHI in early 2010 and an increase in our core non-seasonal products as a result of inventory levels normalizing at our distributors during 2009. 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; and
- changes in distributor buying patterns.

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.

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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 2027. 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 commercially 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 United States. 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, 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

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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 31%, 52% and 57% of our total revenue for the years ended December 31, 2010, 2009 and 2008, respectively. We had sales to one distributor for whom sales exceeded 10% of total revenue for the year ended December 31, 2010. This distributor was Cardinal. 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, 2010, 2009 and 2008, sales of our infectious disease products (including influenza test sales) accounted for 61%, 78% and 72%, 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.

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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 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 royalty payments based on specified product sales. Royalty expenses under these licensing agreements collectively totaled $7.8 million, $13.5 million and $10.5 million for the years ended December 31, 2010, 2009 and 2008, respectively. We believe we will continue to incur substantial royalty expenses relating to future sales of our products.

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,

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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.

We currently have a $120.0 million senior secured syndicated credit facility, which matures on October 8, 2013. Our senior credit facility bears interest for base rate loans at a rate equal to (i) the higher of (a) the lender s prime rate and (b) the Federal funds rate plus one-half of one percent, plus (ii) the applicable rate or for Eurodollar rate loans the interest rate is equal to (i) the Eurodollar rate, plus (ii) the applicable rate. The applicable rate is generally determined in accordance with a performance pricing grid based on our leverage ratio and ranges from 0.50% to 1.75% for base rate loans and from 1.50% to 2.75% for Eurodollar rate loans. The current applicable rate is subject to adjustment, as described below. The agreement governing our senior credit facility includes certain customary limitations on our operations and activities, 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 annual capital expenditures. We are also subject to financial covenants which include a funded debt to EBITDA ratio (as defined in our senior credit facility, with adjusted EBITDA generally calculated as earnings before, among other adjustments, interest, taxes, depreciation and amortization) not to exceed 3:00 to 1:00 as of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:50 to 1:00 as of the end of each fiscal quarter. If we fail to comply with these restrictions or covenants, our senior credit facility could become due and payable prior to maturity. As of December 31, 2010 we were in compliance with all financial covenants.

During the third quarter of 2010, our senior credit facility was amended to exclude the application of the funded debt to adjusted EBITDA ratio and interest coverage ratio for the measurement date occurring on December 31, 2010. The amendment also increased the applicable interest rate under the credit agreement by 50 basis points commencing on the date of the amendment and remaining effective until the first quarter of 2011 in which we are required to deliver our quarterly compliance certificate showing compliance with both financial covenants. If such compliance is demonstrated, the applicable rate will decrease by 50 basis points.

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 (for which we may obtain waivers). As of December 31, 2010, we had $72.0 million outstanding under our $120.0 million 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

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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.

Since 2008, the global capital and credit markets have 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 United States 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. These competitors include, among others, Alere Inc. (formerly, Inverness Medical Innovations, Inc.) (ALR), Beckman Coulter Primary Care Diagnostics (Beckman), Fisher Scientific Corporation (Fisher), Sekisui Medical Co., LTD. (Sekisui), Becton Dickinson and Company (Becton), Meridian Bioscience, Inc. (Meridian) and Chemicon International, Inc. (Chemicon). 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

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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% excise tax on certain transactions, including many U.S. sales of medical devices, which we expect will include U.S. sales of our test kits. This tax is scheduled to take effect in 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 would 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 or restrictions on our business. In addition, because of the nature of the penalties provided for in some of these environmental regulations, we could be required

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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.

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.

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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 15%, 21%, and 15% of our total revenue for the years ended December 31, 2010, 2009 and 2008, 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 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

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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. We do not currently hedge against exchange rate fluctuations, which means that we are fully exposed to exchange rate changes.

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. In addition, our independent registered public accounting firm must attest to the effectiveness of our interal controls over financial reporting. How companies are implementing these requirements, including internal control reforms, if any, to comply with Section 404 s requirements, and how independent registered public accounting firms are applying these requirements and testing companies internal controls, remain subject to uncertainty. 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, 2008 and December 31, 2010, the closing price of our common shares, as reported by the Nasdaq Global Market, has ranged from a low of $7.92 to a high of $17.77. 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, 2010:

- approximately 28.5 million of our common shares were issued of which approximately 28.1 million are generally tradable in the public markets without restrictions;

approximately 3.2 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 $12.25; and
we had approximately 412,000 of our common shares underlying restricted stock.

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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 (as occurred in January 2011), or issuances of securities convertible into or exercisable for our common shares or other equity linked securities, including preferred stock or warrants, will 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.
- Under our stockholder rights plan, the acquisition of 15% or more of our outstanding common shares by any person or group, unless approved by our Board of Directors, will trigger the right of our stockholders (other than the acquiror of 15% or more of our common shares) to acquire additional common shares, and, in certain cases, the stock of the potential acquiror, at a 50% discount to market price, thus increasing the acquisition cost to a potential acquiror.
- 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 acquiror from gaining effective economic or voting control.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our 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 10,000 square feet of additional office space in San Diego and that lease expires in 2011 with options to extend the lease for two additional two-year periods. 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 72,500 square feet of manufacturing, administrative and research and development space in Athens, Ohio. The Athens, Ohio lease expires in 2012 with an option to extend for one additional five-year period. Finally, we lease approximately 3,900 square feet of laboratory and office space in Cleveland, Ohio. The Cleveland, Ohio lease expires in 2011.

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

None.

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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, 2010	$11.00	$14.51
September 30, 2010	10.84	13.61
June 30, 2010	10.56	15.10
March 31, 2010	12.63	15.57
December 31, 2009	$12.57	$16.59
September 30, 2009	13.43	17.77
June 30, 2009	8.29	14.67
March 31, 2009	7.92	13.42

As of February 22, 2011, we had approximately 536 common stockholders of record. No cash dividends were declared for our common stock during the fiscal years ended in 2010 or 2009, 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 3 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, 2010.

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, 2010		$		$ 10,300,000
November 1 November 30, 2010				10,300,000
December 1 December 31, 2010				10,300,000
Total		$		$ 10,300,000

(1) In June 2005, we announced that our Board of Directors authorized us to repurchase up to $25.0 million in shares of our common stock under our stock repurchase program. In March 2007, we announced that our Board of Directors authorized us to repurchase up to an additional $25.0 million in shares of our common stock under our stock repurchase program. In December 2008, we announced that our Board of Directors authorized us to repurchase up to an additional $25.0 million in shares of our common stock under our stock repurchase program. In December 2009, we announced that our Board of Directors authorized us to repurchase up to an additional

$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 December 2, 2011 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, 2005 and ending December 31, 2010. The graph assumes an initial investment of $100 on December 31, 2005 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.

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COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Quidel Corporation, the NASDAQ Composite Index
and the NASDAQ Pharmaceutical Index

* $100 Invested on 12/31/05 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

Company/Index	Base Period 12/31/05	12/31/06	12/31/07	12/31/08	12/31/09	12/31/10
Quidel Corporation	**$100.00**	$126.58	$180.95	$121.47	$128.07	$134.29
NASDAQ Composite	**100.00**	111.74	124.67	73.77	107.12	125.93
NASDAQ Pharmaceutical	**100.00**	101.61	94.58	87.40	95.29	101.44

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,				
	2010(1)	**2009**	**2008**	**2007**	**2006**
	(in thousands, except per share data)				
Total revenues	$ 113,339	$ 164,282	$ 128,132	$ 118,065	$ 106,015
Costs and expenses					
Cost of sales (excludes amortization of intangible assets)(2)	51,489	55,218	50,206	48,573	44,818
Amortization of inventory fair value adjustment from acquisition	1,118				
Total cost of sales (excludes amortization of intangible assets)(2)	52,607	55,218	50,206	48,573	44,818

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	Year ended December 31,				
	2010(1)	2009	2008	2007	2006
	(in thousands, except per share data)				
Research and development	24,571	12,526	11,147	12,855	13,047
Sales and marketing	23,972	23,347	20,898	18,491	16,966
General and administrative	18,471	16,783	12,786	13,167	12,770
Amortization of intangible assets from acquired businesses	5,366				
Amortization of intangible assets from licensed technology	1,365	1,364	4,476	5,493	4,580
Business acquisition and integration costs, and restructuring charges	2,276	2,495			
Total costs and expenses	128,628	111,733	99,513	98,579	92,181
Operating (loss) income	(15,289)	52,549	28,619	19,486	13,834
Other (expense) income					
Interest income	214	372	1,686	1,891	1,408
Interest expense	(2,345)	(767)	(671)	(736)	(757)
Other (expense) income		(5)	135	(117)	545
Total other (expense) income	(2,131)	(400)	1,150	1,038	1,196
(Loss) income from continuing operations before (benefit) provision for income taxes	(17,420)	52,149	29,769	20,524	15,030
(Benefit) provision for income taxes	(6,149)	19,266	10,921	6,893	(5,891)
(Loss) income from continuing operations	(11,271)	32,883	18,848	13,631	20,921
Gain from discontinued operations, net of taxes					797
Net (loss) income	$ (11,271)	$ 32,883	$ 18,848	$ 13,631	$ 21,718
Basic (loss) earnings per share:					
Continuing operations	$ (0.39)	$ 1.10	$ 0.59	$ 0.43	$ 0.63
Discontinued operations					0.02
Net (loss) income	(0.39)	1.10	0.59	0.43	0.66
Diluted (loss) earnings per share:					
Continuing operations	$ (0.39)	$ 1.08	$ 0.58	$ 0.41	$ 0.61
Discontinued operations					0.02
Net (loss) income	(0.39)	1.08	0.58	0.41	0.63
Shares used in basic per share calculation	28,582	29,964	31,853	32,028	32,985
Shares used in diluted per share calculation	28,582	30,418	32,612	32,996	34,367
Balance Sheet Data					

	December 31				
	2010	2009	2008	2007	2006
			(in thousands)		
Cash, cash equivalents and marketable securities	$ 6,788	$ 93,002	$ 57,908	$ 45,489	$ 36,625
Working capital	$ 40,250	$ 96,699	$ 85,592	$ 70,259	$ 53,063
Total assets	$214,593	$166,345	$142,808	$133,838	$127,048
Long-term debt and lease obligations	$ 79,774	$ 6,527	$ 6,137	$ 7,000	$ 7,764
Stockholders equity	$112,521	$126,450	$119,236	$107,703	$103,276
Common shares outstanding	28,514	29,026	31,894	32,706	33,530

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

(2) Excludes amortization of intangible assets of $5.9 million, $1.2 million, $4.0 million, $4.2 million and $1.9 million for the years ended December 31, 2010, 2009, 2008, 2007 and 2006, respectively.

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

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, 2010, 2009 and 2008, we derived approximately 51%, 87% and 84%, 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 31%, 52% and 57% of our total revenue for the years ended December 31, 2010, 2009 and 2008, respectively, were related to sales through our four largest distributors.

For the year ended December 31, 2010, total revenue decreased 31% to $113.3 million from $164.3 million for the year ended December 31, 2009. This was largely driven by a decrease in sales of our influenza products as a result of the influenza pandemic which occurred in 2009 which was partially offset by the acquisition of DHI in early 2010 and an increase in our core non-seasonal products as a result of inventory levels normalizing at our distributors during 2009.

Our primary objective is to create shareholder value by building a broader-based diagnostic company, with products in market segments in which we have significant expertise and know-how.

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

- lateral flow immunoassay tests;
- direct fluorescent assays (DFA) and culture-based tests; and
- molecular diagnostic tests.

Our strategy to accomplish our primary objective includes the following:

- leveraging our current infrastructure to develop and launch new lateral flow and DFA products;
- developing a molecular diagnostics franchise; and
- strengthening our position with distribution partners to gain more emphasis on our products in the United States 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,

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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 of 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.

On February 19, 2010, we acquired Diagnostic Hybrids, Inc. (DHI) a privately-held, *in vitro* diagnostics (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 . We paid approximately $131.2 million in cash to acquire DHI. We paid for the acquisition of DHI using cash and cash equivalents on hand and borrowed $75.0 million under the Senior Credit Facility (as defined below).

Recent Developments

In January 2011, we completed a public offering of 4.6 million shares of our common stock at $13.15 per share. We received proceeds, net of underwriting discounts and commissions, of $57.9 million ($12.43 per share) and expect to incur approximately $0.7 million in related offering expenses. We expect 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.

Outlook

We expect a more normalized influenza season for 2010/2011, therefore, we expect to see sales steadily increase from the fourth quarter of 2010 into the first quarter of 2011. We anticipate gross margins will trend higher year over year as a result of a product mix shift to include higher influenza sales in fiscal year 2011 compared to fiscal year 2010 which was adversely impacted by the lack of an influenza season in the first quarter of 2010. The acquisition of DHI continues to build upon and diversify our revenue base and we expect the acquisition to lessen the effect of seasonality on our business quarter to quarter. 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

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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, 2010 and 2009

Total Revenues

During 2010, in connection with the acquisition of DHI, we changed our disease state classifications within our one reportable segment to better reflect current business activities and taking into account the products sold by DHI. The information for all prior periods presented have been restated to conform to the current presentation. The following table compares total revenues for the years ended December 31, 2010 and 2009 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2010	2009	$	%
Infectious disease net product sales	$ 68,869	$ 127,961	$ (59,092)	(46)%
Women s health net product sales	32,246	25,497	6,749	26%
Gastrointestinal disease net product sales	5,967	4,023	1,944	48%
Other net product sales	3,864	5,551	(1,687)	(30)%
Royalty, license fees and grant revenue	2,393	1,250	1,143	91%
Total revenues	$ 113,339	$ 164,282	$ (50,943)	(31)%

The decrease in total revenues was primarily due to a decrease in sales of our influenza products as a result of the influenza pandemic which occurred in 2009. Partially offsetting the decrease in total revenues was an increase in sales as a result of the acquisition of DHI which contributed $34.7 million; including $26.8 million in infectious disease, $4.9 million in women s health, $2.2 million in gastrointestinal disease and $0.8 million in grant revenue. In addition, total revenues relating to our core non-seasonal products increased as a result of inventory levels normalizing at our distributors during 2009.

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 5% to $52.6 million, or 46% of total revenues, for the year ended December 31, 2010 compared to $55.2 million, or 34% of total revenues, for the year ended December 31, 2009. The absolute dollar decrease in cost of sales is primarily related to decreased costs associated with lower influenza sales year-over-year partially offset by the acquisition of DHI which contributed $12.7 million. The increase in cost of sales as a percentage of total revenue was related to an unfavorable product mix driven primarily by lower influenza sales and the amortization of an inventory fair value adjustment associated with the acquisition of DHI.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2010 and 2009 (in thousands, except percentages):

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	For the year ended December 31,					
	2010		2009			
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues	Increase (decrease) $	%
Research and development	$24,571	22%	$12,526	8%	$12,045	96%
Sales and marketing	23,972	21%	23,347	14%	625	3%
General and administrative	18,471	16%	16,783	10%	1,688	10%
Amortization of intangible assets from acquired businesses	5,366	5%			5,366	N/A
Amortization of intangible assets from licensed technology	1,365	1%	1,364	1%	1	N/A
Business acquisition and integration costs, and restructuring charges	2,276	2%	2,495	2%	(219)	(9)%

Research and Development Expense

Research and development expense increased $9.1 million as a result of the acquisition of DHI. In addition, there was an increase in project costs and employee compensation associated with the development of potential new technologies and with products under development.

Sales and Marketing Expense

Sales and marketing expense increased $2.9 million as a result of the acquisition of DHI. The overall increase was partially offset by a decrease in sales commissions and product promotions associated with a lower sales volume for 2010 (excluding the impact from the acquisition of DHI) as a result of the influenza pandemic which occurred in 2009. 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 $2.6 million as a result of the acquisition of DHI. The overall increase was partially offset by a decrease in employee incentives associated with a lower sales volume for 2010 (excluding the impact from the acquisition of DHI) compared to 2009 and a decrease in transition costs from those incurred in the first quarter of 2009 relating to the hiring of our Chief Executive Officer.

Amortization of Intangible Assets from Acquired Businesses

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

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

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 acquisition and integration activities. During the fiscal year ended December 31, 2009, we recorded a restructuring charge of $2.0 million, comprised of severance costs and costs associated with vacating the unutilized portion of our Santa Clara facility, which is net of a $0.2 million stock-based compensation expense reversal for certain terminated employees.

Other Income (Expense)

The decrease in interest income to $0.2 million as of December 31, 2010 from $0.4 million as of December 31, 2009 was primarily related to a decrease in our average cash balance and a decrease in the average interest rate. 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, 2010 and 2009 were 35.3% and 36.9%, respectively. We recognized an income tax benefit of $6.1 million for the year ended December 31, 2010 compared to income tax expense of $19.3 million for the year ended December 31, 2009. 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 is 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. Income tax expense for 2009 includes a net reduction primarily related to the use of research and development credits and application of a

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manufacturing tax deduction.

Comparison of years ended December 31, 2009 and 2008

Total Revenues

The following table compares total revenues for the years ended December 31, 2009 and 2008 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2009	2008	$	%
Infectious disease net product sales	$ 127,961	$ 92,426	$ 35,535	38%
Women s health net product sales	25,497	26,179	(682)	(3)%
Gastrointestinal disease net product sales	4,023	4,403	(380)	(9)%
Other net product sales	5,551	3,834	1,717	45%
Royalty, license fees and grant revenue	1,250	1,290	(40)	(3)%
Total revenues	$ 164,282	$ 128,132	$ 36,150	28%

The increase in total revenues was primarily driven by an increase in global sales of our influenza products. The decrease in sales of our women s health products was primarily related to our 2008 strategic sales initiative that affected distributor ordering patterns and had a resulting increase in their inventories. The increase in our other product sales category was a result of an increase in sales of our veterinary products.

The revenue from royalty income and license fees for all periods primarily relate to royalty payments earned on our patented technologies utilized by third parties.

Cost of Sales

Cost of sales increased 10% to $55.2 million, or 34% of total revenue, for the year ended December 31, 2009 compared to $50.2 million, or 39% of total revenues, for the year ended December 31, 2008. The absolute dollar increase is primarily related to the variable nature of direct costs (material and labor) associated with the 28% increase in total revenues. The percentage decrease in cost of sales as a percentage of total revenue was largely due to a more favorable product mix as our influenza tests are typically higher margin products for us.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2009 and 2008 (in thousands, except percentages):

	For the year ended December 31,					
	2009		2008			
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues	Increase (decrease) $	%
Research and development	$12,526	8%	$11,147	9%	$ 1,379	12%
Sales and marketing	23,347	14%	20,898	16%	2,449	12%
General and administrative	16,783	10%	12,786	10%	3,997	31%
Amortization of intangible assets from licensed technology	1,364	1%	4,476	4%	(3,112)	(70)%
Business acquisition and integration costs, and	2,495	2%			2,495	N/A

restructuring charges

Research and Development Expense

The increase in research and development expense was due primarily to an increase in overall employee compensation for 2009 as a result of an increase in headcount, an increase in costs associated with the development of potential new technologies and products under development and an increase in clinical studies related to our influenza products.

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Sales and Marketing Expense

The increase in sales and marketing expense was due primarily to an increase in promotions related to our influenza products, an overall increase in sales personnel and related programs and expenses and an increase in sales commissions associated with a higher sales volume for 2009 compared to 2008. Other key components of this expense relate to continued investment in assessing future product extensions and enhancements and market research.

General and Administrative Expense

The increase in general and administrative expense was due primarily to an increase in overall incentive-based compensation and increased expenses as a result of hiring new executives in 2009. In addition, increased costs incurred in connection with our new credit facility.

Amortization of Intangible Assets from Licensed Technology

The amortization of intangible assets decreased primarily due to the full amortization of a license agreement in December 2008.

Business Acquisition and Integration Costs, and Restructuring Charges

We incurred $0.5 million in expenses in the fourth quarter of 2009 relating to the acquisition of DHI. The expenses relate primarily to professional fees. We recorded a restructuring charge of $2.0 million, comprised of severance costs and costs associated with vacating the unutilized portion of our Santa Clara facility, during the fiscal year ended December 31, 2009, which is net of a $0.2 million stock-based compensation expense reversal for certain terminated employees.

Other Income (Expense)

The decrease in interest income to $0.4 million as of December 31, 2009 from $1.7 million as of December 31, 2008 was primarily related to the decrease in interest rates. Interest expense relates to interest paid on our lease obligation associated with our San Diego facility.

Income Taxes

The effective tax rate for the years ended December 31, 2009 and 2008 were 36.9% and 36.7%, respectively. We recognized income tax expense of $19.3 million for the year ended December 31, 2009 as compared to $11.0 million for the year ended December 31, 2008, which was largely driven by the increase in taxable income from 2008 to 2009. Income tax expense for 2009 includes a net reduction primarily related to the use of research and development credits and application of a manufacturing tax deduction. Income tax expense for 2008 includes a net reduction primarily related to deductions associated with investments in foreign subsidiaries and a manufacturing tax deduction.

Liquidity and Capital Resources

As of December 31, 2010, our principal sources of liquidity consisted of $6.8 million in cash and cash equivalents. Our working capital as of December 31, 2010 was $40.3 million.

Cash used for our operating activities was $10.3 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 $134.5 million during the year ended December 31, 2010 primarily related to the purchase of DHI. In addition, we used approximately $7.5 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.

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We are currently planning approximately $9.0 million in capital expenditures over the next 12 months. The primary purpose for our capital expenditures is to acquire manufacturing equipment, implement facility improvements, and for the purchase or development of information technology. We plan to fund these capital expenditures with cash flow from operations and other available sources of liquidity. We have $0.1 million in firm purchase commitments with respect to such planned capital expenditures as of the date of filing this report.

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.

Our $120.0 million senior secured syndicated credit facility (the Senior Credit Facility) matures on October 8, 2013. The Senior Credit Facility bears interest for base rate loans at a rate equal to (i) the higher of (a) the lender s prime rate and (b) the Federal funds rate plus one-half of one percent, plus (ii) the applicable rate or for Eurodollar rate loans the interest rate is equal to (i) the Eurodollar rate, plus (ii) the applicable rate. The applicable rate is generally determined in accordance with a performance pricing grid based on our leverage ratio and ranges from 0.50% to 1.75% for base rate loans and from 1.50% to 2.75% for Eurodollar rate loans. The current applicable rate is subject to adjustment, as described below. 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 annual capital expenditures. We are also subject to financial covenants which include a funded debt to EBITDA ratio (as defined in the Senior Credit Facility, with adjusted EBITDA generally calculated as earnings before, among other adjustments, interest, taxes, depreciation and amortization) not to exceed 3:00 to 1:00 as of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:50 to 1:00 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. 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, 2010, we had $72.0 million outstanding under the Senior Credit Facility which was borrowed in connection with the acquisition of DHI. As of December 31, 2010, we were in compliance with all financial covenants.

During the first quarter of 2010, the Senior Credit Facility was amended for various matters, including amending the credit and security agreement to (i) permit the acquisition of all capital stock of DHI, (ii) allow certain indebtedness and liens related to the DHI acquisition to remain outstanding after the close of the acquisition and (iii) to amend the Senior Credit Facility to increase the aggregate amount of permitted stock repurchases thereunder. In addition, during the third quarter of 2010, the Senior Credit Facility was amended to exclude the application of the funded debt to adjusted EBITDA ratio and interest coverage ratio for the measurement date occurring on December 31, 2010. The amendment also increased the applicable interest rate under the credit agreement by 50 basis points commencing on the date of the amendment and remaining effective until we deliver our compliance certificate for the first quarter of 2011 showing compliance with both financial covenants. If such compliance is demonstrated, the applicable rate will decrease by 50 basis points.

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, 2010 and 2009, 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.

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Commitments

As of December 31, 2010, our future commitments and 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)	$ 11,234	$ 1,100	$ 2,227	$ 2,259	$ 5,648
Operating lease obligations(2)	4,486	1,696	1,987	803	
Total contractual obligations	15,720	2,796	4,214	3,062	5,648
Borrowing under line of credit(3)	72,000		72,000		
Note payable to state agency(4)	1,708	211	434	452	611
Total commitments	73,708	211	72,434	452	611
Total commitments and contractual obligations	$ 89,428	$ 3,007	$ 76,648	$ 3,514	$ 6,259

(1) Reflects our lease obligation on the approximately 78,000 square-foot San Diego facility in place as of December 31, 2010. 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, 2010. In the fourth quarter of 2009, we entered into an agreement to lease approximately 10,000 square feet of additional office space in San Diego with a lease term through October 2011. The operating lease at our Santa Clara location has a lease term through November 2014. Future minimum lease payments are included in the table above.

(3) Reflects our $72.0 million borrowing under the line of credit which is scheduled to expire on October 8, 2013.

(4) Reflects our note payable to the State of Ohio which was assumed as part of the acquisition of DHI.

We have entered into various licensing agreements, which largely require royalty payments based on specified product sales. These agreements encompass the majority of our visual lateral flow products, the most significant of which expires in early 2015. Royalty expenses under these licensing agreements, which are charged to cost of sales, collectively totaled $7.8 million, $13.5 million and $10.5 million for the years ended December 31, 2010, 2009 and 2008, respectively. We believe we will continue to incur substantial royalty expenses relating to future sales of our products.

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

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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. 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. We also earn income from grants for research and commercialization activities which are recognized during the period in which the revenue is earned and the amount is determinable. Income earned from licensing and grant activities are a component of total revenues in the accompanying Consolidated Statements of Operations.

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 estimated fair value of each stock option was determined on the date of grant using the Black-Scholes option valuation model. Compensation expense for restricted stock awards (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 our common stock on the grant date.

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 volatility of our stock has decreased in recent fiscal periods, and as a result in fiscal year 2008, we changed our look-back period in determining volatility to the third quarter of 2005. 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 collectibility 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 demand forecast is greater than our actual 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

Intangible assets with definite lives are amortized over their estimated useful lives. 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;

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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, 2010 and determined that no impairment of goodwill or in-process research and development existed.

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 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. 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 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 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 we believe that we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcome of examinations by tax authorities in determining the adequacy of our provision for income taxes. See Note 4 in the 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, 2010 and 2009, deferred tax assets do not include $2.2 million 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 $2.2 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 $72.0 million outstanding under our Senior Credit Facility at December 31, 2010. The weighted average interest rate on these borrowings is currently 2.51%. 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 $0.7 million. Based on our market risk sensitive instruments outstanding at December 31, 2010 and 2009, 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, 2010, 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.

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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.

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, 2010 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, 2010 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, 2010.

The effectiveness of our internal control over financial reporting as of December 31, 2010 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.

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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, 2010, 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, 2010, 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, 2010 and 2009, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2010 of Quidel Corporation and our report dated February 25, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP
San Diego, California
February 25, 2011

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Item 9B. Other Information

2011 Annual Meeting of Stockholders

The Company s 2011 Annual Meeting of Stockholders will be held on Tuesday, May 10, 2011, beginning at 8:30 a.m. (local time) at the Hyatt Regency, La Jolla at Aventine, 3777 La Jolla Village Drive, San Diego, California, 92122.

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 2011 Proxy Statement, which will be filed with the SEC no later than May 2, 2011. Information with respect to executive officers is included under Item 1 on pages 10-12 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 2011 Proxy Statement, which will be filed with the SEC no later than May 2, 2011.

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 2011 Proxy Statement, which will to be filed with the SEC no later than May 2, 2011.

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 Equity Compensation Plans and Security Ownership of Certain Beneficial Owners and Management to be contained in our 2011 Proxy Statement, which will be filed with the SEC no later than May 2, 2011.

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 2011 Proxy Statement, which will be filed with the SEC no later than May 2, 2011.

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 2011 Proxy Statement, which will be filed with the SEC no later than May 2, 2011.

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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

Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets as of December 31, 2010 and 2009	F-2
Consolidated Statements of Operations for the years ended December 31, 2010, 2009 and 2008	F-3
Consolidated Statements of Stockholders Equity for the years ended December 31, 2010, 2009 and 2008	F-4
Consolidated Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008	F-5
Notes to Consolidated Financial Statements	F-6

(2) Financial Statement Schedules

The following Financial Statement Schedule of Quidel Corporation for the years ended December 31, 2010, 2009 and 2008 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.

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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 25, 2011

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 25, 2011
/s/ John M. Radak John M. Radak	Chief Financial Officer, (Principal Financial Officer and Accounting Officer)	February 25, 2011
/s/ Mark A. Pulido Mark A. Pulido	Chairman of the Board	February 25, 2011
/s/ Thomas D. Brown Thomas D. Brown	Director	February 25, 2011
/s/ Kenneth F. Buechler Kenneth F. Buechler	Director	February 25, 2011
/s/ Rodney F. Dammeyer Rodney F. Dammeyer	Director	February 25, 2011
/s/ Mary Lake Polan Mary Lake Polan	Director	February 25, 2011
/s/ Jack W. Schuler Jack W. Schuler	Director	February 25, 2011

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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, 2010 and 2009, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, 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, 2010, 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 25, 2011 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP
San Diego, California
February 25, 2011

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

	December 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,788	$ 89,003
Marketable securities		3,999
Accounts receivable, net	13,477	9,717
Inventories	17,707	15,038
Deferred tax asset current	7,159	6,018
Income tax receivable	8,344	
Prepaid expenses and other current assets	2,552	2,448
Total current assets	56,027	126,223
Property, plant and equipment, net	31,755	21,251
Goodwill	71,013	6,470
Intangible assets, net	53,675	1,943
Deferred tax asset non-current		9,065
Other non-current assets	2,123	1,393
Total assets	$ 214,593	$ 166,345
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,715	$ 5,212
Accrued payroll and related expenses	3,013	5,187
Accrued royalties	2,262	5,513
Current portion of lease obligation	280	234
Income taxes payable		6,151
Other current liabilities	5,507	7,227
Total current liabilities	15,777	29,524
Long term debt	73,498	
Lease obligation, net of current portion	6,276	6,527
Deferred tax liability non-current	2,313	
Income taxes payable	2,937	2,360
Other non-current liabilities	1,271	1,484
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $.001 par value per share; 5,000 shares authorized, none issued or outstanding at December 31, 2010 and 2009		
Common stock, $.001 par value per share; 50,000 shares authorized, 28,514 and 29,026 shares issued and outstanding at December 31, 2010 and 2009, respectively	29	29
Additional paid-in capital	109,802	112,426
Accumulated other comprehensive income		34
Retained earnings	2,690	13,961

Total stockholders equity	112,521	126,450
Total liabilities and stockholders equity	$ 214,593	$ 166,345

See accompanying Notes.

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

	Year ended December 31,		
	2010	**2009**	**2008**
Total revenues	$ 113,339	$ 164,282	$ 128,132
Costs and expenses			
Cost of sales (excludes amortization of intangible assets of $5.9 million, $1.2 million and $4.0 million, respectively)	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 of $5.9 million, $1.2 million and $4.0 million, respectively)	52,607	55,218	50,206
Research and development	24,571	12,526	11,147
Sales and marketing	23,972	23,347	20,898
General and administrative	18,471	16,783	12,786
Amortization of intangible assets from acquired businesses	5,366		
Amortization of intangible assets from licensed technology	1,365	1,364	4,476
Business acquisition and integration costs, and restructuring charges	2,276	2,495	
Total costs and expenses	128,628	111,733	99,513
Operating (loss) income	(15,289)	52,549	28,619
Other (expense) income			
Interest income	214	372	1,686
Interest expense	(2,345)	(767)	(671)
Other (expense) income		(5)	135
Total other (expense) income	(2,131)	(400)	1,150
(Loss) income before provision for taxes	(17,420)	52,149	29,769
(Benefit) provision for income taxes	(6,149)	19,266	10,921
Net (loss) income	$ (11,271)	$ 32,883	$ 18,848
Basic (loss) earnings per share	$ (0.39)	$ 1.10	$ 0.59
Diluted (loss) earnings per share	$ (0.39)	$ 1.08	$ 0.58
Shares used in basic per share calculations	28,582	29,964	31,853
Shares used in diluted per share calculations	28,582	30,418	32,612

See accompanying Notes.

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QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock		Additional paid-in	Accumulated other comprehensive	Retained earnings (accumulated	Total stockholders	Total comprehensive income
	Shares	Amount	capital	income	deficit)	equity	(loss)
				(in thousands)			
Balance at December 31, 2007	32,706	$ 33	$ 145,440	$	$ (37,770)	$ 107,703	$ 13,631
Issuance of common stock under equity compensation plans	661		3,346			3,346	
Cancellation of common stock under equity compensation plans	(131)		(1)			(1)	
Income tax benefit due to exercise/disposition of employee stock options			6,476			6,476	
Stock-based compensation expense			2,677			2,677	
Purchase of common stock	(1,342)	(1)	(19,812)			(19,813)	
Net income					18,848	18,848	18,848
Balance at December 31, 2008	31,894	32	138,126		(18,922)	119,236	$ 18,848
Issuance of common stock under equity compensation plans	551		1,860			1,860	
Cancellation of common stock under equity compensation plans	(240)		(2)			(2)	
Income tax benefit due to exercise/disposition of employee stock options			1,429			1,429	
Stock-based compensation expense			4,522			4,522	
Unrealized gains on marketable securities				34		34	34
Purchase of common stock	(3,179)	(3)	(33,509)			(33,512)	

Net income					32,883	32,883	32,883
Balance at December 31, 2009	29,026	29	112,426	34	13,961	126,450	$ 32,917
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	
Realized gains on marketable securities				(34)		(34)	
Purchase of common stock	(740)	(1)	(9,180)			(9,181)	
Net loss					(11,271)	(11,271)	(11,271)
Balance at December 31, 2010	28,514	$ 29	$ 109,802	$	$ 2,690	$ 112,521	$ (11,271)

See accompanying Notes.

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QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2010	2009	2008
	(in thousands)		
OPERATING ACTIVITIES			
Net (loss) income	$ (11,271)	$ 32,883	$ 18,848
Adjustments to reconcile net (loss) income to net cash (used for) provided by operating activities:			
Depreciation, amortization and other	12,326	6,366	8,681
Stock-based compensation expense	5,158	4,522	2,677
Gain on sale of assets	9		
Change in deferred tax assets and liabilities	1,273	2,629	8,071
Excess tax benefit from share-based compensation	(248)	(1,429)	(6,476)
Changes in assets and liabilities:			
Accounts receivable	3,079	15,603	(2,157)
Inventories	2,420	(3,336)	(665)
Income tax receivable	(4,196)		
Prepaid expenses and other current assets	690	(1,395)	536
Accounts payable	(2,595)	924	(547)
Accrued payroll and related expenses	(2,636)	2,468	(1,622)
Accrued royalties	(3,515)	2,854	(630)
Accrued income taxes payable	(6,151)	7,458	
Other current and non-current liabilities	(4,636)	3,296	2,225
Net cash (used for) provided by operating activities	(10,293)	72,843	28,941
INVESTING ACTIVITIES			
Acquisitions of property and equipment	(7,477)	(6,850)	(4,118)
Purchase of business, net of cash acquired of $3.1 million	(128,142)		
Purchases of marketable securities		(3,999)	
Proceeds from sale of marketable securities	3,999		
Acquisition of intangibles	(3,000)	(250)	(360)
Other assets	81	(126)	49
Net cash used for investing activities	(134,539)	(11,225)	(4,429)
FINANCING ACTIVITIES			
Proceeds from issuance of common stock, net of cancellations	1,151	1,858	3,345
Excess tax benefit from share-based compensation	248	1,429	6,476
Payments on lease obligation	(205)	(238)	(765)
Purchase of common stock	(9,181)	(33,512)	(19,813)
Borrowing from line of credit	75,000		
Payments on borrowing from line of credit	(3,000)		
Fees paid to establish line of credit			(1,336)
Other	(1,396)	(60)	
Net cash provided by (used for) financing activities	62,617	(30,523)	(12,093)

Net (decrease) increase in cash and cash equivalents	(82,215)	31,095	12,419
Cash and cash equivalents at beginning of year	89,003	57,908	45,489
Cash and cash equivalents at end of year	$ 6,788	$ 89,003	$ 57,908
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid for interest	$ 2,345	$ 767	$ 671
Cash paid for income taxes	$ 7,711	$ 10,337	$ 3,425
NON-CASH INVESTING ACTIVITIES			
Purchase of license agreements by incurring current liabilities	$ 800	$	$
Purchase of capital equipment by incurring current liabilities	$ 401	$ 234	$ 263

See accompanying Notes.

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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. In preparing the accompanying consolidated financial statements, subsequent events have been evaluated up to and including the date these financial statements were issued.

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.

Marketable Securities The Company considers marketable securities to be available-for-sale . Accordingly, marketable securities are presented at fair value with unrealized gains and losses recorded as a component of stockholders equity. The Company sold all of its marketable securities during the fiscal year ended December 31, 2010.

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 returned good allowances and bad debts. The balance of accounts receivable is net of reserves for bad debts and sales allowances of $1.9 million and $3.3 million at December 31, 2010 and 2009, respectively.

Inventories Inventories are stated at the lower of cost (first-in, first-out method) or market. The Company reviews the components of its inventory on a quarterly basis for excess, obsolete and impaired inventory and makes appropriate dispositions as obsolete stock is identified. Inventories consisted of the following, net of reserves of $0.6 million for year ended December 31, 2010 and $0.1 million for year ended December 31, 2009 (in thousands):

	December 31,	
	2010	**2009**
Raw materials	$ 7,262	$ 5,307
Work-in-process (materials, labor and overhead)	5,375	3,711
Finished goods (materials, labor and overhead)	5,070	6,020
Total inventories	$ 17,707	$ 15,038

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 $5.2 million, $3.8 million and $3.8 million for the years ended December 31, 2010, 2009 and 2008, respectively. Maintenance and minor repairs are charged to operations as incurred.

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

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	December 31,	
	2010	2009
Equipment, furniture and fixtures	$ 46,405	$ 38,377
Building and improvements	26,382	19,478
Land	1,080	1,080
Computer software development costs	466	
	74,333	58,935
Less: Accumulated depreciation and amortization	(42,578)	(37,684)
Total property, plant and equipment, net	$ 31,755	$ 21,251

Intangible Assets Intangible assets are recorded at cost and amortized, except for indefinite-lived intangibles such as goodwill and in-process research and development, on a straight-line basis over their estimated useful lives. Intangible assets consisted of the following (dollar amounts in thousands):

	Weighted-Average Remaining Life	December 31, 2010			December 31, 2009		
Description	(years)	Gross Assets	Accumulated Amortization	Net	Gross Assets	Accumulated Amortization	Net
Goodwill	Indefinite	$ 74,461	$ (3,448)	$ 71,013	$ 9,918	$ (3,448)	$ 6,470
Purchased technology	7.3	52,670	(10,801)	41,869	6,100	(6,100)	
Customer relationships	7.1	5,450	(587)	4,863			
In-process research and development	Indefinite	2,110		2,110			
License agreements	11.2	20,340	(17,174)	3,166	17,340	(15,958)	1,382
Patent and trademark costs	12.8	5,013	(3,562)	1,451	3,623	(3,332)	291
Favorable lease	3.8	1,700	(1,484)	216	1,700	(1,430)	270
Total goodwill and intangible assets		$ 161,744	$ (37,056)	$ 124,688	$ 38,681	$ (30,268)	$ 8,413

Amortization expense was $6.7 million, $1.4 million and $4.5 million for the years ended December 31, 2010, 2009 and 2008, respectively.

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

Years Ended December 31,	Amortization Expense
2011	$ 7,146
2012	6,945
2013	6,859
2014	6,854
2015	6,804
Thereafter	16,957
Total	$ 51,565

The Company completed its annual evaluation for impairment of goodwill and in-process research and development as of December 31, 2010 and determined that no impairment of goodwill or in-process research and development existed. 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.

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

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	December 31,	
	2010	2009
Accrued liability for technology licenses	$ 2,300	$
Customer incentives	1,740	4,824
Current portion of note payable to state agency	211	
Accrued professional fees	92	345
Stock repurchases not settled as of December 31, 2009		1,234
Other	1,164	824
Total other current liabilities	$ 5,507	$ 7,227

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. Royalty income from the grant of license rights is recognized during the period in which the revenue is earned and the amount is determinable from the licensee. The Company also earns income from grants for research and commercialization activities which are recognized during the period in which the revenue is earned and the amount is determinable. Income earned from licensing and grant activities are a component of total revenues in the accompanying Consolidated Statements of Operations.

Research and Development Costs Research and development costs are largely charged to operations as incurred. Software development costs and certain costs related to research and development projects have been capitalized as part of property, plant and equipment and are depreciated over their expected useful life.

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 $1.2 million, $1.3 million and $1.5 million for the years ended December 31, 2010, 2009 and 2008, respectively.

Advertising Costs Advertising costs are expensed as incurred. Advertising costs were $1.0 million, $1.1 million and $0.8 million for the years ended December 31, 2010, 2009 and 2008, 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.

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, accrued liabilities and outstanding balances owed under the line of credit approximate their fair values due to their short-term nature. Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of trade accounts receivable. The Company establishes reserves for estimated uncollectible accounts and believes its reserves are adequate.

Product Warranty The Company generally sells products with a limited product warranty and certain limited indemnifications. The accrual and the related expense for known issues were not significant as of and for the fiscal years presented. 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 accrual based on 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 estimated fair value of each stock option was determined on the date of grant using the Black-Scholes option valuation model. Compensation expense for restricted stock awards (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 our common stock on the grant date.

Computation of (Loss) Earnings Per Share Basic (loss) earnings per share were computed by dividing net (loss) earnings by the weighted-average number of common shares outstanding, including vested restricted stock awards, during the period. Diluted earnings per share reflects the potential dilution that could occur if the earnings were divided by the weighted-average number of common shares and potentially dilutive common shares from outstanding stock options as well

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as unvested restricted stock awards. Potential dilutive common shares were calculated using the treasury stock method and represent incremental shares issuable upon exercise of the Company s outstanding stock options and unvested restricted stock awards. The Company has historically awarded restricted stock with both service-based as well as performance-based vesting provisions. Stock awards that are performance-based are not included in the calculation of basic (loss) earnings per share until the performance criteria are met and the stock award has vested. For the year ended December 31, 2009, the Company included 0.1 million performance-based stock awards in the computation of diluted (loss) earnings per share as the performance criteria had been met, but the stock awards had not yet vested. For periods in which the Company incurs losses, potentially dilutive shares are not considered in the calculation of net loss per share as their effect would be anti-dilutive. For periods in which the Company has earnings, out-of-the-money stock options (*i.e.*, the average stock price during the period is below the exercise price of the stock option) are not included in diluted earnings per common share as their effect would be anti-dilutive.

During the year ended December 31, 2010, 3.5 million of outstanding stock options and unvested restricted stock awards were not included in the computation of diluted loss per share as the effect on diluted loss per common share would be anti-dilutive. During the years ended December 31, 2009 and 2008, 1.6 million and 0.8 million shares of outstanding stock options were not included in the computation of diluted earnings per common share for 2009 and 2008, respectively, because the option exercise price was greater than the average market price of the common stock, and therefore, the effect on diluted earnings per common share would be anti-dilutive.

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

	Year ended December 31,		
	2010	**2009**	**2008**
Shares used in basic (loss) earnings per share (weighted-average common shares outstanding)	28,582	29,964	31,853
Effect of dilutive stock options and restricted stock awards		454	759
Shares used in diluted (loss) earnings per share calculation	28,582	30,418	32,612

Comprehensive (Loss) Income Comprehensive (loss) income includes unrealized gains and losses excluded from the Company s Consolidated Statements of Operations. The components of accumulated other comprehensive (loss) income for the year ended December 31, 2009 are unrealized gains 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, 2010, the remaining accrual is classified as other current liabilities of $0.2 million and other non-current liabilities of $0.5 million 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 January 2, 2011. For ease of reference, the calendar quarter end dates are used herein.

Note 2. Acquisition

On February 19, 2010, the Company acquired Diagnostic Hybrids, Inc. (DHI) a privately-held, *in vitro* diagnostics (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

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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 (as defined below). 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 is 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 is 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

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.

	Weighted-average

(in thousands)	Fair value	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	

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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.

	Year ended December 31,	
(in thousands, except per share data)	**2010**	**2009**
Pro forma total revenues	$ 119,044	$ 213,336
Pro forma net (loss) income	$ (13,989)	$ 35,318
Pro forma basic net (loss) earnings per share(1)	$ (0.49)	$ 1.18
Pro forma diluted net (loss) earnings per share(1)	$ (0.49)	$ 1.16

(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 3. Line of Credit

The Company currently has a $120.0 million senior secured syndicated credit facility (the Senior Credit Facility), which matures on October 8, 2013. The Senior Credit Facility bears interest for base rate loans at a rate equal to (i) the higher of (a) the lender s prime rate and (b) the Federal funds rate plus one-half of one percent, plus (ii) the applicable rate or for Eurodollar rate loans the interest rate is equal to (i) the Eurodollar rate, plus (ii) the applicable rate. The applicable rate is generally determined in accordance with a performance pricing grid based on the Company s leverage ratio and ranges from 0.50% to 1.75% for base rate loans and from 1.50% to 2.75% for Eurodollar rate loans (weighted average interest rate of 2.51% at December 31, 2010). The current applicable rate is subject to adjustment, as described below. 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 annual capital expenditures. The Company is also subject to financial covenants which include a funded debt to EBITDA ratio (as defined in the Senior Credit Facility, with adjusted EBITDA generally calculated as earnings before, among other adjustments, interest, taxes, depreciation and amortization) not to exceed 3:00 to 1:00 as of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:50 to 1:00 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. 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. At December 31, 2010, the Company had $72.0 million outstanding under the Senior Credit Facility which was borrowed in connection with the acquisition of DHI. As of December 31, 2010, the Company was in compliance with all financial covenants.

During the first quarter of 2010, the Senior Credit Facility was amended for various matters, including amending the credit and security agreement to (i) permit the acquisition of all capital stock of DHI, (ii) allow certain indebtedness and liens related to the DHI acquisition to remain outstanding after the close of the acquisition and (iii) to amend the Senior Credit Facility to increase the aggregate amount of permitted stock repurchases thereunder. In addition, during the third quarter of 2010, the Senior Credit Facility was amended to exclude the application of the funded debt to adjusted EBITDA ratio and interest coverage ratio for the measurement date occurring on December 31, 2010. The amendment also increased the applicable interest rate under the credit agreement by 50 basis points commencing on the date of the amendment and remaining effective until the Company delivers its compliance certificate for the first quarter of 2011 showing compliance with both financial covenants. If such compliance is demonstrated, the applicable rate will decrease by 50 basis points.

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Note 4. Income Taxes

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

	December 31,		
	2010	2009	2008
United States	$ (17,420)	$ 52,224	$ 29,671
Foreign		(75)	98
	$ (17,420)	$ 52,149	$ 29,769

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

	December 31,		
	2010	2009	2008
Current:			
Federal	$ (6,976)	$ 16,059	$ 7,677
State	159	2,007	1,650
Total current (benefit) provision	(6,817)	18,066	9,327
Deferred:			
Federal	1,622	(21)	1,287
State	(954)	1,221	307
Total deferred (benefit) provision	668	1,200	1,594
(Benefit) provision for income taxes	$ (6,149)	$ 19,266	$ 10,921

Significant components of the Company s deferred tax assets and liabilities as of December 31, 2010 and 2009 are shown below (in thousands).

	December 31,	
	2010	2009
Deferred tax assets:		
Net operating loss carryforwards	$ 8,204	$
Acquired intangibles	4,778	2,997
Sale-leaseback, net	2,134	2,528
Capitalized research and development costs	438	1,344
Allowance for returns and discounts	1,343	3,182
Stock compensation	5,698	2,325
Tax credit carryforwards	853	24
Depreciation		129
Other, net	3,058	2,554
Total deferred tax assets	26,506	15,083
Valuation allowance for deferred tax assets		
Deferred tax assets, net of valuation allowance	26,506	15,083

Deferred tax liabilities:		
Acquired intangibles	(18,777)	
Depreciation	(2,883)	
Total deferred tax liabilities	(21,660)	
Net deferred tax assets and liabilities	$ 4,846	$ 15,083

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.

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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, 2010 and 2009, deferred tax assets do not include $2.2 million of these excess tax benefits from employee stock option exercises that are a component of the Company s NOL carryforwards. Additional paid-in capital would be increased up to an additional $2.2 million if such excess tax benefits are realized.

As of December 31, 2010, the Company had federal NOL carryforwards of approximately $26.6 million which will expire at various dates through December 31, 2030, unless previously utilized. The Company has federal research credits of $0.6 million which will expire at various dates through December 31, 2030, unless previously utilized. The Company has gross state research credits of $3.5 million which do not expire.

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

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

	Year ended December 31,		
	2010	**2009**	**2008**
(Benefit) tax expense at statutory tax rate	$ (6,095)	$ 18,255	$ 10,417
State (benefit) taxes, net of federal (benefit) tax	(734)	2,270	1,588
Permanent differences	1,173	(788)	(153)
Federal and state research credits current year	(952)	(835)	(569)
Liability for uncertain tax positions	74	299	152
Foreign taxes and foreign (income) losses not benefited (taxed)		23	(34)
Impact of change in federal and state tax rate on revaluing DTAs	548	310	(594)
Other	(163)	(268)	114
	$ (6,149)	$ 19,266	$ 10,921

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):

	2010	**2009**
Beginning balance	$ 6,983	$ 6,510
Increases related to prior year tax positions	346	184
Increases related to current year tax positions	623	372
Increases related to DHI pre-acquisition items	319	
Decreases due to settlements	(92)	
Other	(94)	(83)
Ending balance	$ 8,085	$ 6,983

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. It is reasonably possible that the Company s unrealized tax benefits will decrease by $0.3 million over the next 12 months. Included in the unrecognized tax benefits of $7.0 million at December 31, 2009 was $5.6 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 $0.2 million of interest and penalties associated with uncertain tax positions as of December 31, 2010 and an immaterial amount as of December 31, 2009.

The Company is subject to periodic audits by domestic and foreign tax authorities. The Company s federal tax years for 1995 and forward are subject to examination by the U.S. authorities due to the carry forward of unutilized net operating

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losses and research and development credits. With few exceptions, the Company s tax years 1999 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 5. Stockholders Equity

Preferred Stock. The Company s certificate of incorporation, as amended, authorizes the issuance of up to five million preferred shares. The Board of Directors is authorized to fix the number of shares of any series of preferred stock and to determine the designation of such shares. However, the amended certificate of incorporation specifies the initial series and the rights of that series. No shares of preferred stock were outstanding as of December 31, 2010 and 2009.

Stockholder Rights Plan. The Board of Directors of the Company adopted a Stockholder Rights Plan, effective December 31, 1996 and as amended and restated, effective May 24, 2002 and then again on December 29, 2006 (the Rights Plan), which provides for a dividend of one right (a Right) to purchase fractions of shares of the Company s Series C Junior Participating Preferred Stock for each share of the Company s common stock. Under certain conditions involving an acquisition by any person or group of 15% or more of the Company s common stock, the Rights permit the holders (other than the 15% holder) to purchase the Company s common stock at a 50% discount upon payment of an exercise price of $24 per Right. In addition, in the event of certain business combinations, the Rights permit the purchase of the common stock of an acquirer at a 50% discount. Under certain conditions, the Rights may be redeemed by the Board of Directors in whole, but not in part, at a price of $.005 per Right. The Rights have no voting privileges and are attached to and automatically trade with the Company s common stock. The Rights shall expire on December 31, 2011, unless earlier triggered, redeemed or exchanged.

Restricted Stock. For the year ended December 31, 2010, the Company granted approximately 0.2 million shares of restricted common stock to officers and management, all of which vest over a four-year period. For the year ended December 31, 2009, the Company granted approximately 0.2 million shares of restricted common stock to officers and management, all of which vest over a four-year period. For the year ended December 31, 2008, the Company granted approximately 0.1 million shares of restricted common stock to a newly hired officer which vest over a three-year period.

Until the restrictions lapse, ownership of the affected shares of restricted stock granted to the Company s officers is conditional upon continuous employment with the Company. During the restricted period, holders of restricted stock have full voting rights with respect to their shares of restricted stock, even though the restricted stock 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 may be 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.

Restricted Stock Units. During the years ended December 31, 2010, 2009 and 2008, 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 the grants of restricted stock units was $0.2 million for the years ended December 31, 2010, 2009 and 2008, respectively.

Stock Options. The Company grants options 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 outstanding which were issued under each of these equity incentive plans to certain employees and directors, which 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, 2010, approximately 2.1 million shares remained available for grant under the 2010 Plan.

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, 2010, 916,686 shares had been sold under the Plan, leaving 93,229 shares available for future issuance.

Share Repurchase Program. In May 2005, the Company s Board of Directors authorized the Company to repurchase up to $25.0 million in shares of its common stock. In March 2007, the Company s Board of Directors authorized

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the Company to repurchase up to an additional $25.0 million in shares of the Company s common stock under this program. In December 2008, the Company s Board of Directors authorized the Company to repurchase up to an additional $25.0 million in shares of the Company s common stock under this program. In December 2009, the Company s Board of Directors authorized the Company to repurchase up to an additional $25.0 million in shares of the Company s common stock under this program. Shares of the Company s common stock repurchased under this program will no longer be deemed outstanding upon repurchase and will be returned to the pool of authorized shares. As of December 31, 2010, the Company had repurchased approximately 7.9 million shares under this program, at a cost of approximately $89.7 million.

Shares Reserved for Future Issuance. At December 31, 2010, approximately 5.3 million shares of common stock were reserved under the Company s equity incentive plans, and 0.1 million were reserved for purchases under the ESPP.

Note 6. Stock-Based Compensation

Compensation expense related to the Company s share-based awards for the years ended December 31, 2010, 2009 and 2008 was $5.2 million, $4.5 million and $2.7 million, respectively, of which $4.0 million, $2.8 million and $2.3 million, respectively, related to stock options and $1.2 million, $1.7 million and $0.4 million, respectively, related to restricted stock awards (stock awards).

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,		
	2010	2009	2008
Cost of sales	$ 0.6	$ 0.6	$ 0.3
Research and development	0.6	0.5	0.4
Sales and marketing	0.4	0.3	0.1
General and administrative	3.6	3.3	1.9
Restructuring charges		(0.2)	
	$ 5.2	$ 4.5	$ 2.7

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

Stock Options

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 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,		
	2010	2009	2008
Risk-free interest rate	2.40%	1.88%	2.58%
Expected option life (in years)	4.89	4.65	4.54
Volatility rate	0.52	0.52	0.50
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 volatility of the Company s stock has decreased in recent fiscal periods, and as a result in fiscal year 2008, the

Company changed the look-back period in determining volatility to the third quarter of 2005. 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.

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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 $6.86, $4.85 and $7.37 for options granted during the years ended December 31, 2010, 2009 and 2008, respectively. The total intrinsic value was $0.8 million, $2.4 million and $5.6 million for options exercised during the years ended December 31, 2010, 2009 and 2008, respectively. As of December 31, 2010, total unrecognized compensation expense related to stock options was approximately $5.2 million and the related weighted-average period over which it is expected to be recognized is approximately 2.3 years. The maximum contractual term of the Company s stock options is ten years.

A summary of the status of stock option activity for the years ended December 31, 2008, 2009 and 2010 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, 2008	1,729	$ 7.55		
Granted	632	16.61		
Exercised	(554)	5.61		
Cancelled	(41)	9.41		
Outstanding at December 31, 2008	1,766	11.36		
Granted	1,682	10.78		
Exercised	(346)	4.64		
Cancelled	(277)	15.77		
Outstanding at December 31, 2009	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	7.50	$ 8,504
Vested and expected to vest at December 31, 2010	2,440	$ 12.25	7.28	$ 6,632
Exercisable at December 31, 2010	974	$ 12.38	5.71	$ 2,851
Available for future grant at December 31, 2010	2,093			

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. Compensation expense for stock awards is measured at the grant date and recognized ratably over the vesting period.

A summary of the status of stock awards activity for the years ended December 31, 2008, 2009 and 2010 is as follows (in thousands, except price data):

		Weighted-Average

	Shares	Grant Date Fair Value
Nonvested at January 1, 2008	555	$ 7.75
Granted	125	17.11
Vested	(57)	6.18
Forfeited	(129)	11.47
Nonvested at December 31, 2008	494	9.33
Granted	183	11.94
Vested	(161)	5.86
Forfeited	(298)	11.15
Nonvested at December 31, 2009	218	11.58
Granted	248	14.12
Vested	(99)	12.85
Forfeited	(16)	11.02
Nonvested at December 31, 2010	351	$ 14.02

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The total amount of unrecognized compensation expense related to nonvested stock awards as of December 31, 2010 was approximately $1.9 million, which is expected to be recognized over a weighted-average period of approximately 2.4 years.

Note 7. Commitments and Contingencies

Leases

The Company leases its facilities and certain equipment. Commitments for minimum rentals under non-cancelable leases at the end of 2010 are as follows (in thousands):

Years ending December 31,	Operating Leases	Lease Obligation
2011	$ 1,696	$ 1,100
2012	1,110	1,110
2013	877	1,117
2014	803	1,125
2015		1,134
Thereafter		5,648
Total minimum lease payments	$ 4,486	11,234
Less amount representing interest		(4,678)
Present value of lease obligation		6,556
Less current portion		(280)
Long-term lease obligation		$ 6,276

Rent expense under operating leases totaled approximately $1.8 million for the year ended December 31, 2010, $0.8 million for the year ended December 31, 2009 and $0.8 million for the year ended December 31, 2008. In the fourth quarter of 2009, the Company entered into a new operating lease to rent approximately 10,000 square feet of additional office space in San Diego with a lease term through October 2011. The operating lease at the Company s Santa Clara location has a lease term through November 2014. The operating lease at the Company s Athens, Ohio location expires in 2012 with an option to extend the lease for one additional five-year period. The operating lease at the Company s Cleveland, Ohio location expires in 2011.

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. The Company s lease for its approximately 78,000 square-foot facility in San Diego, CA was initially for 15 years, with options to extend the lease for up to two additional five-year periods.

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, $1.4 million and $1.4 million for each of the three years ended December 31, 2010, 2009 and 2008, respectively.

Contracts

The Company has entered into various licensing agreements, which largely require royalty payments based on specified product sales. These agreements encompass the majority of the Company s visual lateral flow products, the most significant of which expires in early 2015. The Company has a royalty agreement with Alere Inc. (formerly, Inverness Medical Innovations, Inc.), which requires ongoing royalty payments of 8.5% on the majority of the Company s current products. Royalty expenses, which are charged to cost of sales under these licensing agreements, totaled $7.8 million,

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$13.5 million and $10.5 million for the years ended December 31, 2010, 2009 and 2008, respectively. As of December 31, 2010 and 2009, $2.3 million and $5.5 million, respectively, were recorded as accrued royalties in the accompanying Consolidated Balance Sheets. During the fourth quarter of 2006, the Company entered into a cross-licensing agreement with another company and paid $6.5 million, which was amortized over the life of the agreement through December 31, 2008. The Company believes it will continue to incur substantial royalty expenses relating to future sales of its products.

Legal

The Company is involved in 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.

Note 8. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented 15%, 21%, and 15% of total revenue for the years ended December 31, 2010, 2009 and 2008, respectively. As of December 31, 2010 and 2009, balances due from foreign customers, in U.S. dollars, were $1.5 million and $7.2 million, respectively.

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

	Year ended December 31,		
	2010	**2009**	**2008**
Customer:			
A	12%	17%	18%
B	8%	15%	19%
C	7%	10%	7%
D	4%	10%	13%
	31%	52%	57%

As of December 31, 2010 and 2009, accounts receivable from individual customers with balances due in excess of 10% of total accounts receivable totaled $3.2 million and $6.8 million, respectively.

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

	Long-lived assets December 31,		Total revenue year ended December 31,		
	2010	**2009**	**2010**	**2009**	**2008**
United States operations					
Domestic	$ 31,755	$ 21,251	$ 95,964	$ 130,021	$ 109,081
Foreign			17,375	34,261	19,051
Total	$ 31,755	$ 21,251	$ 113,339	$ 164,282	$ 128,132

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

	Year ended December 31,		
	2010	**2009**	**2008**
Infectious disease	$ 68,869	$ 127,961	$ 92,426
Women s health	32,246	25,497	26,179
Gastrointestinal disease	5,967	4,023	4,403

Other	3,864	5,551	3,834
	$ 110,946	$ 163,032	$ 126,842

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Note 9. Fair Value Measurement

The Company s valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs are generally developed internally, utilizing management s estimates, assumptions and specific knowledge of the assets/liabilities and related market assumptions. The fair value of our cash equivalents are determined based on Level 1 inputs, which consist of quoted prices in active markets for identical assets. For the fiscal year ended December 31, 2009, the Company held marketable securities which consisted of commercial paper with maturities no greater than 180 days. Realized gains on the sale of the marketable securities were not material for the fiscal year ended December 31, 2010.

Note 10. 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 $0.7 million, $0.4 million and $0.6 million to the 401(k) Plan during the year ended December 31, 2010, 2009 and 2008, respectively.

Note 11. Subsequent Event

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 expects to incur approximately $0.7 million in related offering expenses. The Company expects 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.

The following unaudited pro forma consolidated balance sheet reflects adjustments to the consolidated balance sheet for the year ended December 31, 2010 to give effect to the sale by the Company of the 4.6 million shares in the offering and the application of the net proceeds, at the public offering price of $13.15 per share, as if the transaction had occurred on December 31, 2010.

	December 31, 2010	Pro forma Adjustments(1)	Pro forma December 31, 2010
Cash and cash equivalents	$ 6,788	$ 57,236	$ 64,024
Working capital	$ 40,250	$ 57,236	$ 97,486
Total assets	$214,593	$ 57,236	$271,829
Stockholders equity	$112,521	$ 57,236	$169,757
Common shares outstanding	28,514	4,600	33,114

(1) Represents the amount of net proceeds received from the issuance of 4.6 million shares of the Company s common stock. Proceeds of $57.2 million is net of estimated offering expenses, which primarily consist of accounting and legal fees.

Note 12. Selected Quarterly Financial Data (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
2010				
Total revenues	$28,379	$25,026	$28,225	$31,709
Cost of sales (excludes amortization of intangible assets)	13,353	12,636	12,807	13,811
Gross profit (1)	14,172	10,828	13,699	16,179

Total costs and expenses	32,194	32,556	31,574	32,304
Net loss	(2,517)	(2,467)	(5,861)	(426)
Basic and diluted net loss per share (3)	(0.09)	(0.09)	(0.21)	(0.02)

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	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
2009				
Total revenues	$16,890	$24,643	$56,152	$66,597
Cost of sales (excludes amortization of intangible assets)	8,424	10,075	17,670	19,049
Gross profit (2)	8,178	14,280	38,194	47,260
Total costs and expenses	21,476	23,540	31,897	34,820
Net income (loss)	(2,801)	637	14,940	20,107
Basic net earnings (loss) per share (3)	(0.09)	0.02	0.50	0.67
Diluted net earnings (loss) per share (3)	(0.09)	0.02	0.50	0.65

(1) Included in 2010 quarterly gross profit is amortization of intangible assets of $0.9 million, $1.6 million, $1.7 million and $1.7 million for the first, second, third and fourth quarters, respectively.

(2) Included in 2009 quarterly gross profit is amortization of intangible assets of $0.3 million for each quarter.

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

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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, 2010:					
Accounts receivable allowance	$3,337	$4,461	$	$ 5,916	$1,882
Year ended December 31, 2009:					
Accounts receivable allowance	$1,512	$9,695	$	$ 7,870	$3,337
Year ended December 31, 2008:					
Accounts receivable allowance	$ 929	$1,608	$	$ 1,025	$1,512

(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.

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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 filed on October 29, 2010.)
3.2	Amended and Restated Bylaws of Quidel Corporation. (Incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K filed on November 8, 2000.)
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 filed on October 29, 2010.)
4.2	Amended and Restated Rights Agreement dated as of December 29, 2006 between Registrant and American Stock Transfer and Trust Company, as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed on January 5, 2007.)
4.3	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 1983 Employee Stock Purchase Plan, as amended. (Incorporated by reference to Exhibit 10.6 to the Registrant s Form 10-Q filed on July 27, 2007.)
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 s Director 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 filed on July 27, 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 2010 Equity Incentive Plan. (Incorporated by reference to Appendix A to the Registrant s Definitive Proxy Statement filed on April 2, 2010.)
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	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.)
10.13	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.)

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Exhibit Number	Description
10.14	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.)
10.15(1)	Employment Agreement, dated as of January 16, 2009, between Registrant and Douglas C. Bryant. (Incorporated by reference to Exhibit 10.1 to the Registrant s Form 8-K filed on January 20, 2009.)
10.16(1)	Stock Option Agreement, dated as of January 16, 2009, between Registrant and Douglas C. Bryant. (Incorporated by reference to Exhibit 10.2 to the Registrant s Form 8-K filed on January 20, 2009.)
10.17(1)	Restricted Stock Agreement, dated as of January 16, 2009, between Registrant and Douglas C. Bryant. (Incorporated by reference to Exhibit 10.3 to the Registrant s Form 8-K filed on January 20, 2009.)
10.18(1)	Agreement Re: Change in Control, dated as of January 16, 2009, between Registrant and Douglas C. Bryant. (Incorporated by reference to Exhibit 10.4 to the Registrant s Form 8-K filed on January 20, 2009.)
10.19(1)	Employment Offer Letter, entered into on June 5, 2008, between Registrant and Robert J. Bujarski. (Incorporated by reference to Exhibit 10.1 to Registrant s Form 8-K filed on June 6, 2008.)
10.20(1)	Agreement Re: Change in Control, entered into on June 5, 2008, between Registrant and Robert J. Bujarski. (Incorporated by reference to Exhibit 10.2 to Registrant s Form 8-K filed on June 6, 2008.)
10.21(1)	Employment Offer Letter, entered into on December 18, 2006, between Registrant and John M. Radak. (Incorporated by reference to Exhibit 10.1 to Registrant s Form 8-K filed on January 3, 2007.)
10.22(1)	Amendment of Employment Offer Letter, dated December 31, 2007, between Registrant and John M. Radak. (Incorporated by reference to Exhibit 10.3 to Registrant s Form 8-K filed on January 3, 2008.)
10.23(1)	Agreement Re: Change in Control, entered into on December 18, 2006, between Registrant and John M. Radak. (Incorporated by reference to Exhibit 10.2 to Registrant s Form 8-K filed on January 3, 2007.)
10.24(1)	Amendment of Agreement Re: Change in Control, dated December 31, 2007, between Registrant and John M. Radak. (Incorporated by reference to Exhibit 10.10 to Registrant s Form 8-K filed on January 3, 2008.)
10.25(1)	Agreement Re: Change in Control, entered into on June 25, 2007, between Registrant and Scot M. McLeod. (Incorporated by reference to Exhibit 10.3 to Registrant s Form 8-K filed on June 26, 2007.)
10.26(1)	Amendment of Agreement Re: Change in Control, dated December 31, 2007, between Registrant and Scot M. McLeod. (Incorporated by reference to Exhibit 10.9 to Registrant s Form 8-K filed on January 3, 2008.)
10.27(1)	Change in Control Agreement dated July 19, 2004 between Registrant and Michael J. Beck. (Incorporated by reference to Exhibit 10.35 to Registrant s Form 10-Q for the quarter ended June 30, 2004.)

10.28(1)	Amendment of Agreement Re: Change in Control, dated December 31, 2007, between Registrant and Michael J. Beck. (Incorporated by reference to Exhibit 10.6 to Registrant s Form 8-K filed on January 3, 2008.)
10.29(1)	Agreement Re: Change in Control, entered into on November 7, 2008, between Registrant and John D. Tamerius, Ph.D. (Incorporated by reference to Exhibit 10.1 to Registrant s Form 8-K filed on November 7, 2008.)
10.30(1)	Employment Offer Letter, dated June 22, 2009, between Quidel Corporation and Timothy T. Stenzel. (Incorporated by reference to Exhibit 10.1 to Registrant s Form 10-Q filed on October 21, 2009.)
10.31(1)	Agreement Re: Change in Control, entered into on September 1, 2009, between Quidel Corporation and Timothy T. Stenzel. (Incorporated by reference to Exhibit 10.2 to Registrant s Form 10-Q filed on October 21, 2009.)
10.32(1)	Employment Offer Letter, dated as of January 10, 2010, between Quidel Corporation and David R. Scholl, Ph.D. (Incorporated by reference to Exhibit 10.1 to Registrant s Form 8-K filed on January 11, 2010.)
10.33(1)	Agreement Re: Change in Control, dated February 19, 2010, between Registrant and David Scholl. (Incorporated by reference to Exhibit 10.2 to Registrant s Form 8-K filed on February 19, 2010.)
10.34(1)	2009 Cash Bonuses for the Company s Executive Officers. (Incorporated by reference to Exhibit 10.2 to Registrant s Form 8-K filed on January 22, 2010.)

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Exhibit Number	Description
10.35(1)	Registrant s 2010 Equity Incentive Program for the Company s Executive Officers, effective as of January 18, 2010. (Incorporated by reference to Exhibit 10.1 to Registrant s Form 8-K filed on January 22, 2010.)
10.36(1)	2010 Annual Base Salaries for the Company s Executive Officers, effective as of March 1, 2010. (Incorporated by reference to Exhibit 10.1 to Registrant s Form 8-K filed on March 1, 2010.)
10.37(1)	Q4 2010 Employee Deferred Compensation Program for Quidel Corporation. (Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed on September 8, 2010.)
10.38(1)	2011 Employee Deferred Bonus Compensation Program for Quidel Corporation. (Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed on December 17, 2010.)
10.39(1)*	2011 Leadership Incentive Compensation Plan (Cash) for Quidel Corporation.
10.40	Credit Agreement, by and among 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 October 8, 2008. (Incorporated by reference to Exhibit 10.1 to Registrant s Form 10-Q filed on July 23, 2009.)
10.41	Security Agreement by and among Registrant, as Borrower, direct and indirect domestic subsidiaries of Borrower, each additional grantor that may become a party thereto and Bank of America, N.A., as Agent, dated as of October 8, 2008. (Incorporated by reference to Exhibit 10.2 to Registrant s Form 10-Q filed on July 23, 2009.)
10.42	First Amendment to Credit Agreement and to Security Agreement, dated as of February 19, 2010, by and among the Registrant, the lenders on the signature pages thereof, Bank of America, N.A., as agent for the lenders, and each of the Guarantors listed on the signature pages thereof. (Incorporated by reference to Exhibit 10.1 to Registrant s Form 8-K filed on February 19, 2010.)
10.43	Second Amendment to Credit Agreement, dated as of September 27, 2010, by and among Quidel Corporation, the financial institutions listed on the signature pages thereof and Bank of America, N.A., as agent for the lenders, and each of the guarantors listed on the signature pages thereof. (Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed on September 29, 2010.)
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification by Principal Executive Officer of 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 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 Registrant pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith

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