QUIDEL CORP /DE/
Form 10-K
March 04, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2007

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)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act: Common Stock, $0.001 par value, and accompanying Preferred Shares Purchase Rights

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 ý

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 ý

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 ý 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 ý	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $498,616,112 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 20, 2008, 32,727,204 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 2008 Annual Meeting of Stockholders (to be held on May 13, 2008) are incorporated by reference into Part III, Items 10, 11, 12, 13 and 14 of this Annual Report on Form 10-K.

A Warning About Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially. 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, the length and severity of cold and flu seasons, our ability to realize revenue from the delayed 2007-2008 flu season, uncertainty surrounding the detection of novel influenza viruses involving human specimens, adverse changes in the competitive and economic conditions in domestic and international markets, actions of our major distributors, technological changes and uncertainty with research and technology development, including any future molecular-based technology, the reimbursement system currently in place and future changes to that system, manufacturing and production delays or difficulties, adverse actions or delays in product reviews by the U.S. Food and Drug Administration (the "FDA"), intellectual property, product liability, environmental or other litigation, 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 sales or market penetration of our new products. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," and similar words, although some forward-looking statements are expressed differently. The risks described under "Risk Factors" in 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.

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 commenced our operations in 1979 and launched our first products, dipstick-based pregnancy tests, in 1984. Our product base and technology platforms have expanded through internal development and acquisitions of other products and technologies. We have a leadership position in the development, manufacturing and marketing of rapid diagnostic solutions at the professional point-of-care ("POC") in infectious diseases and reproductive and women's health. We focus on POC testing solutions specifically developed for the physician office lab ("POL") and acute care markets globally. We sell our products to professionals for use in physician offices, hospitals, clinical laboratories, retail clinics and wellness screening centers. Our POC testing solutions are designed to provide specialized results that meet two important value criteria that we have branded as Quidel Value Build ("QVB "):

Clinical validation: the enabling of rapid patient management decisions leading to improved treatment and outcomes.

Economic validation: the reduction of overall costs associated with patient testing with emphasis upon critical reimbursement and payer performance criteria.

We market our POC products in the U.S. through a network of national and regional distributors, supported by a direct sales force. Internationally, we sell and market primarily in Japan and Europe by channeling products through distributor organizations and sales agents. In addition, in January 2008, we entered into an agreement with bioMerieux S.A. ("bioMerieux") to form a long-term global alliance in the area of rapid clinical diagnostics for the point-of-care. Starting in May 2008, bioMerieux will be the exclusive distributor of all our current rapid diagnostic tests in all regions with the exception of the U.S., Japan and Scandinavia.

In addition to our rapid, POC diagnostic business, we also develop research products through our Specialty Products Group (the "SPG"), with an emphasis on potential future rapid test applications. The SPG is currently responsible for more than 100 of our clinical and research products used worldwide in reference laboratories and in research applications at leading universities and biotechnology companies. The SPG revenues, income and assets are less than 10% of our overall operations.

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

Business Strategy

We believe that the trend among healthcare providers to adopt POC testing continues to increase, and demographic changes, reimbursement policies, a shortage of skilled laboratory workers and the availability of clinically valuable tests will increase growth in this diagnostic category. More and more employers, health plans and payers are recognizing that POC testing is a cost-effective means for improving the quality of care and patient satisfaction. Continuous improvements in technologies are resulting in a growing number of new diagnostic tests that combine high levels of accuracy with rapid, easy-to-use product formats. It is our mission to further expand our significant leadership position in POC rapid diagnostics. In order to accomplish this mission, our strategy is to:

provide clinicians with validated, evidence-based proof which encompasses the clinical efficacy and economic efficiency of our rapid POC tests for the professional market. In conjunction with our QVB commitment, we expect to present ongoing information that supports the adoption of rapid POC testing;

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

drive growth by establishing dedicated distributor partnerships with aggressive performance metrics and expanding our sales organization to assure physician and laboratorian satisfaction through direct relationships with Integrated Delivery Networks and hospitals;

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

as healthcare management continues to move closer to the patient, develop test formats which meet the rigorous requirements for over-the-counter test performance;

continue creation of strong global alliances to assure leadership in key markets;

drive profit through further refinement of our manufacturing efficiencies and productivity improvements, with continued focus on profitable products and markets and our effort to create exceptional competency in new product development process management;

continue to focus our research and development efforts on three areas: 1) new proprietary product platform development, 2) the creation of improved products and new products for existing markets, and 3) products developed under collaborations with other companies for new and existing markets; and

identify and commercialize new markers, products and collaborations in bone health through the SPG. We believe we can capitalize upon our existing microwell plate platform core competencies and long-standing collaborations with key researchers worldwide, which may assist with identifying, developing and producing unique diagnostic and research products targeted at disease state mastery. We characterize this direction as a dedicated focus on Research to Rapids . These assays and reagents may be used by customers throughout the continuum-of-care in the diagnosis of disease and monitoring of therapy to the development of novel therapeutics.

Diagnostic Test Kit Industry Overview

The Overall Market for *In Vitro* Diagnostics

The worldwide market for *in vitro* diagnostic, or IVD, products was estimated at approximately $28.0 billion in 2005, and is segmented by the particular test discipline. The largest market segments are immunodiagnostics testing and instrument-based clinical chemistry, which account for approximately 31% and 21% of the total IVD market, respectively. Geographically, in 2006, approximately 40% of total IVD revenues were generated in the U.S., while Europe and Asia accounted for approximately 37% and 18%, respectively.

Customers for IVD products are primarily large centralized laboratories, independent reference laboratories or hospital-based facilities. In the U.S., these central laboratories account for approximately 75% of the revenues generated by IVD products.

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 more effective immediate care.

Hospitals in the U.S. have progressively sought to reduce the length of patient stays and, consequently, the proportion of cases seen as outpatients has increased. If the U.S. experience is representative of future trends, emergency departments and other critical care units such as intensive care units, operating rooms, trauma and cardiac centers are increasingly becoming the principal centers for the management of moderate and severe acute illness. In the U.S., there are between 110 and 120 million emergency room visits annually.

The over-the-counter market for IVD self-testing has not been materially affected by these trends. The worldwide over-the-counter market was estimated to grow to $4.8 billion by 2005. Two test categories, glucose monitoring for diabetes and pregnancy, currently dominate this market segment.

The Professional POC Market

POC testing for certain diseases has become an accepted adjunct to central laboratory and self-testing. The professional POC market is comprised of two general segments: decentralized testing

in non-institutional settings such as physicians' offices and hospital testing (emergency rooms and bedside). Hospital POC testing is accepted and growing and is generally an extension of the hospital's central laboratory.

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 for smaller practice physicians' offices. We believe POC testing out-of-hospital is increasing due to its clinical benefit, cost-effectiveness and patient satisfaction.

Total revenues from the rapid, non-instrument-based professional POC market were estimated at approximately $483 million in 2005 in the U.S. The growth in POC testing in the U.S. is in part due to evolving technological improvements creating high quality tests with laboratory accuracy and POC ease-of-use, which are capable of being granted a waiver under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). A CLIA-waived test is defined as a simple laboratory test which employs methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible and/or pose no reasonable risk of harm to the patient if the test is performed incorrectly. CLIA-waived tests may be used in physician office laboratories, as well as acute care, urgent care and hospital facilities. In 2006, an estimated 91,637, or 79%, of physician office laboratories had a CLIA waiver.

Products

A majority of our total revenues relate to three product families. For the years ended December 31, 2007, 2006 and 2005, we derived approximately 81%, 82% and 78%, respectively, of our total revenues from sales of our influenza, Group A Strep and pregnancy tests. We expect that these three product families will continue to account for a substantial portion of our total revenues and any material reduction in supply, demand or pricing of these product families would have a material adverse effect on our business, operating results and financial condition.

For the years ended December 31, 2007, 2006 and 2005, export sales to unaffiliated customers constituted approximately 14%, 20% and 25%, respectively, of total revenue. The export sales were primarily to customers in Japan and Europe. We expect that export sales will represent a growing portion of our total revenue in the foreseeable future.

We provide rapid POC and other diagnostic tests under the following brand names: QuickVue®, QuickVue+®, QuickVue Advance® and Metra®. Our rapid POC diagnostic tests and our diagnostic and research markers participate in the following medical and wellness categories:

Infectious Diseases

Influenza. Our 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 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. In December 2005, we announced FDA clearance for several new claims for our QuickVue® Influenza A+B test, including 94% sensitivity for detecting type A influenza with nasal swabs versus culture and 90% specificity.

Group A Strep. 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. 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 to be used to aid in the diagnosis of Group A Streptococcal infection.

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.

Reproductive and Women's Health

Pregnancy. Our QuickVue® pregnancy tests are used in both the physicians office lab and the acute care settings. The early detection of pregnancy enables the physician and patient to institute proper care, helping to promote the health of both the woman and the developing embryo. Our QuickVue® 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.

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. Our QuickVue® Chlamydia test is a lateral flow immunoassay for the rapid, qualitative detection of Chlamydia from endocervical swab and cytology brush specimens. The test is intended for use as an aid in the presumptive diagnosis of Chlamydia.

Bacterial Vaginosis. Each year millions of women seek treatment of genital infections generally known as infectious vaginitis. One of the most common forms of infectious vaginitis is bacterial vaginosis ("BV"), a condition which, if left untreated, can lead to serious clinical complications, including pre-term births, pelvic inflammatory disease, infections following gynecological surgeries and an increased risk of contracting HIV. Our QuickVue® Advance G. Vaginalis test, launched in July 2002, is an enzyme activity test for use in the detection of *Gardnerella vaginalis* Proline IminoPeptidase ("PIP") activity in vaginal fluid specimens from patients suspected of having bacterial vaginosis.

Other

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 iFOB test in late December 2005.

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.

Bone Health. Osteoporosis is a systemic skeletal disease characterized by low bone mass and deterioration of the microarchitecture of bone tissue, with a consequent increase in bone fragility and susceptibility to fractures. The risk for fracture increases exponentially with age. A key set of

parameters in the monitoring of osteoporosis, both before and after therapy, are biochemical markers of bone metabolism. As a leader in the field of bone markers, we produce both clinical and research products for the assessment of osteoporosis and the evaluation of bone resorbtion/formation, which, including our metabolic bone markers, are used by physicians to monitor the effectiveness of therapy in pharmaceutical and related research.

We have other products which include veterinary products as well as clinical laboratory and research tests used in the measurement of circulating immune complexes, complement deficiencies and complement activation.

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. For the years ended December 31, 2007, 2006 and 2005, total revenue in the first and fourth quarters have combined for 61%, 62% and 62%, respectively. 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, 2007, 2006 and 2005, sales of our infectious disease products accounted for 64%, 65% and 59%, respectively, of total revenue. Sales of our products vary from year to year and quarter to quarter, and can be influenced significantly if distributors attempt to time the onset of an early cold and flu season, or if they initiate larger orders in anticipation of a more severe cold and flu season. Our influenza products have a two-year shelf life, which may also lead a distributor to initiate its purchases earlier in the flu season. While we believe that the severity, length and timing of the onset of the cold and flu season will continue to impact sales of our infectious disease products, there can be no assurance that our future sales of these products will necessarily follow historical patterns.

Research and Development

We continue to focus our research and development efforts on three areas: 1) new proprietary product platform development, 2) the creation of improved products and new products for existing markets, and 3) products developed under collaborations with other companies for new and existing markets. Our immunoassay development program is evaluating a variety of leading technology and product licensing opportunities from a number of academic research departments and other organizations.

As part of our focus on Research to Rapids , the SPG preferentially targets markers with potential downstream POC application in selected disease states. Several candidate tests have been developed on microwell platforms and are currently marketed and sold to clinicians and researchers. The SPG is strategically focused on developing clinical proof around these markers and demonstrating their utility in a variety of pathologies. We currently market and sell these products both directly and through select distributors throughout the world under our Quidel® and Metra® brands.

Research and development expenses were approximately $12.9 million, $13.0 million and $12.8 million for the years ended December 31, 2007, 2006 and 2005, respectively. There were no significant customer-sponsored research activities during the years ended December 31, 2007, 2006 and 2005. During the second quarter of 2005, our joint development agreement with a third party was terminated and the remaining deferred revenue balance of $0.9 million was recognized as contract revenue during the second quarter of 2005. 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

We focus on ensuring market leadership and providing points of differentiation by specializing in the diagnosis and monitoring of selected disease states. In order to support our value proposition as a company that markets the highest quality products in support of better medical outcomes, we are highlighting our QVB efforts through the development of new innovations and the communication of new solutions in the field of rapid diagnostic testing. Our QVB program includes significant work in understanding the needs of the end-use customer, building products that meet those needs, providing proof studies to validate rapid diagnostic testing at the point-of-care, and leveraging the work of researchers and key opinion leaders studying our tests and technology to help enhance the health and well being of people around the globe. Our marketing strategy includes ensuring each of our key product portfolios is supported by economic and clinical validation that shows hospitals, laboratories, acute care facilities and POC clinicians that these tests deliver high quality results in a cost-effective manner.

In contrast to the central laboratory market, the U.S. POC market is highly fragmented, with many small or medium-sized customers. We have designed our business strategy around serving the needs of this market segment. To reach these customers, a network of national and regional distributors is utilized and supported by our sales force. We have developed priority status with several of the major distributors in the U.S., resulting in many of our products being the preferred products offered by these distributors.

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 with the exception of influenza testing in the Japanese market. Our partnership with bioMerieux seeks to bring the POC testing, clinical and economic proof and quality of our brand to markets around the globe, enabling acceptance and expansion of POC testing through successful use of our QuickVue® product portfolio.

During 2007, we continued to invest in several key areas: further validation of customer needs through voice of customer studies ("VOC"), expanding clinical research as part of our QVB program and expanding our communications through extensive advertising, direct mail, promotional campaigns and public relations. Our VOC emphasis enables us to better understand the customer's needs and requirements in both domestic and international markets in order to focus our product marketing and distribution partner plans. For example, annual post-season flu market research allows us to measure the success of our messaging to drive adoption as well as identify new product requirements for future application to the product line.

The essential aspect of QVB is building awareness about our products and their performance through the clinical validation value criterion. During 2007, we conducted several clinical studies and/or sponsored others that have resulted in abstracts and posters, which included presentations at the Options VI Influenza International Meeting (Toronto), the Infectious Disease Society of America Annual Meeting (San Diego), the International Conference on Respiratory Infections (Hong Kong), the Clinical Virology Symposium (Clearwater) and at the American Academy of Pediatrics.

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 52%, 59% and 63% of our total revenue for the years ended December 31, 2007, 2006 and 2005, respectively. Even though our distributor mix will likely change from period to period in the future, Cardinal Healthcare Corporation ("Cardinal"), DS Pharma Biomedical Co., Ltd ("DS Pharma") (formerly known as Sumitomo Seiyaku Biomedical Co., Ltd.), National Distribution Corporation ("NDC") and Physician Sales and Services Corporation ("PSS") have historically

accounted for a significant portion of our total revenue. Our sales are affected by fluctuations in the buying patterns of these distributors and the corresponding changes in inventory levels maintained by them. Inventory levels held by these distributors may fluctuate significantly from quarter to quarter. We have limited visibility into or control over forces affecting changes in distributor inventory levels. If total revenue to our significant distributors were to decrease in any material amount in the future, our business, operating results and financial condition could be materially adversely affected.

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

Manufacturing

We have manufacturing operations in San Diego, California and Santa Clara, California. The San Diego facility, our largest manufacturing operation, principally produces our lateral-flow, immunoassay products. The Santa Clara facility manufactures our microtiter plate products.

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 facility has operated under a Quality Management System certified to the International Organization for Standardization ("ISO") 9001 certification. During 2005, we became certified to the ISO 13485:2003 Regulatory Standard as required for medical device manufacturers distributing product within the European Union and other countries. Our facility in Santa Clara, California is also ISO 13485:2003 certified. 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.

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.

In certain instances, we rely on a single source or a limited group of suppliers for certain components and raw materials for our products. Although we seek to reduce our dependence on sole or limited source suppliers, if available or practicable, the partial or complete loss of these sources could have a material adverse effect on our results of operations and damage customer relationships, due to the complexity of the products they supply and the significant amount of time required to qualify new suppliers.

The manufacture of medical diagnostic products is difficult, particularly with respect to the stability and consistency of complex biological components. Because of these complexities, manufacturing difficulties occasionally occur that delay the introduction or supply of products and result in unanticipated manufacturing costs.

Government Regulation

The testing, manufacture and commercialization of our products are subject to regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. Pursuant to the U.S. Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder, the FDA regulates the preclinical and clinical testing, manufacture, labeling, distribution and promotion of medical devices. Noncompliance with applicable requirements can result in, among other matters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the FDA to grant premarket clearance or premarket approval for

devices, withdrawal of marketing clearances or approvals and criminal prosecution. The FDA also has the authority to request a recall, repair, replacement or refund of the cost of any device manufactured or distributed in the U.S. if the device is deemed to be unsafe.

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

Prior to commercialization in the U.S. market, manufacturers must obtain FDA clearance through a premarket notification or premarket approval process, which can be lengthy, expensive and uncertain. The FDA has been requiring more rigorous demonstration of product performance as part of the 510(k) process, including submission of extensive clinical data. It generally takes from three to six months to obtain clearance but may take longer. For example, the FDA may determine that additional information is needed before a clearance determination can be made, which could prevent or delay the introduction of new products into the market. 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, and there can be no assurance that the FDA will grant approval.

We may not be able to obtain the necessary regulatory premarket approvals or clearances for our products on a timely basis, if at all. Delays in receipt of or failure to receive such approvals or clearances, or failure to comply with existing or future regulatory requirements, would have a material adverse effect on our business, financial condition and results of operations.

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's 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 product may have caused or contributed to a death or serious injury, or in which a product 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.

We are subject to routine inspection by the FDA and other state agencies for compliance with applicable federal, state and local regulations. Changes in existing requirements or adoption of new requirements could have a material adverse effect on our business, financial condition and results of operations. We may also incur significant costs in complying with any applicable laws and regulations in the future, resulting in a material adverse effect on our business, financial condition and results of operations.

Our research and development and manufacturing activities involve the controlled use of hazardous materials, including but not limited to biological materials and chemicals such as dimethyl sulfate, sodium nitrite, acetaldehyde, acrylamide, potassium bromate and radionuclides. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. These regulations include federal statutes popularly known as CERCLA, RCRA and the Clean Water Act. Compliance with these laws and regulations is expensive. If any governmental authorities were to impose new environmental regulations requiring compliance in addition to that required by existing regulations, these future environmental regulations could impose substantial costs

on our business. In addition, because of the nature of the penalties provided for in some of these environmental regulations, we could be required to pay substantial fines, penalties or damages in the event of noncompliance with environmental laws or the exposure of individuals to hazardous materials. 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.

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 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, 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 2024 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 determines that relevant patent protection may be obtained. No assurance can be given that patents will be issued to us pursuant to our patent applications in the U.S. or abroad or that our patent portfolio will provide us with a meaningful level of commercial protection.

A large number of individuals and commercial enterprises seek patent protection for technologies, products and processes in fields in or related to our areas of product development. To the extent such efforts are successful, we may be required to obtain licenses and pay significant royalties in order to

exploit certain of our product strategies and avoid a material adverse effect on our business. Licenses may not be available to us at all or, if so available, may not be available on acceptable terms.

We are aware of certain patents issued to various developers of diagnostic products with potential applicability to our diagnostic technology. We have licensed certain rights from certain companies to assist with the manufacturing of certain products. In the future, we expect 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. There can be no assurance that such licenses will be obtainable on commercially reasonable terms, if at all, that any patents underlying such licenses will be valid and enforceable, or that the proprietary nature of any patented technology underlying such licenses will remain proprietary.

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. Despite such efforts, no assurance can be given that the confidentiality of our proprietary information can be maintained. 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 diagnostic products is intense, and diagnostic technologies have been subject to rapid change. We believe that some of the most significant competitive factors in the rapid diagnostic market include convenience, price and product performance as well as the distribution, advertising, promotion and brand name recognition of the marketer. Our success will depend on our ability to remain abreast of technological advances, to introduce technologically advanced products, to effectively market our differentiated value 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. We expect that these laboratories 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 demonstrate that our products provide physicians cost-effective and time-saving alternatives to tests performed in the clinical reference laboratory. This requires that physicians change the way that they are used to handling diagnostic testing.

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. Many of our current and prospective 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, Inverness Medical Innovations, Inc. ("IMA"), Beckman Coulter Primary Care Diagnostics ("Beckman"), Fisher Scientific Corporation ("Fisher"), Genzyme Diagnostics Corporation ("Genzyme"), and Becton Dickinson and Company ("Becton"). Our competitors may succeed in developing or marketing technologies or products that are more effective or commercially attractive than our current or future products or that would render our technologies and products obsolete. Moreover, we may not have the financial resources, technical expertise or

marketing, distribution or support capabilities to compete successfully in the future. In addition, many competitors have made substantial investments in competing technologies that may be more effective than our technologies, or that may prevent, limit or interfere with our ability to make, use or sell our products either in the U.S. or in international markets.

Human Resources

As of December 31, 2007, we had 278 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, 2007 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 five years adversely reflecting on the officer's ability or integrity.

Caren L. Mason, 54, became our President and Chief Executive Officer on August 20, 2004. She has more than 25 years experience in healthcare. Prior to joining us, Ms. Mason provided consultative services for Eastman Kodak Health Imaging as a result of the sale of MiraMedica, Inc., a digital technology, diagnostic imaging company, to Eastman Kodak. She served as President and CEO for MiraMedica, Inc. from April 2002 through September 2003. From January 2000 through June 2001, Ms. Mason served as CEO of eMed Technologies, Inc. of Lexington, Massachusetts, a digital technology, diagnostic imaging company. Prior to joining eMed Technologies, Ms. Mason served as General Manager of the Women's Healthcare business and as a General Manager in various capacities for the Services business of General Electric Medical Systems from July 1996 to January 2000. Ms. Mason's additional healthcare experience includes her tenure with Bayer AG/AGFA from October 1989 to July 1996 where she last served as Senior Vice President for the AGFA Technical Imaging Business Group. Ms. Mason began her career in healthcare with American Hospital Supply/Baxter Healthcare and served in sales, marketing and managerial roles from 1977 through 1988. Ms. Mason is a graduate of Indiana University. She has been a member of the Franciscan Sisters of the Poor Foundation Board of Governors and has also been a member of the Board of Directors for MediServ/GESCI, eMed Technologies, Inc. and MiraMedica, Inc., and currently serves as a member of the Board of Directors of AdvaMed.

John M. Radak, 47, became our Chief Financial Officer on February 1, 2007. Prior to joining us, Mr. Radak was Vice President of Finance and Chief Accounting Officer for Invitrogen Corporation, a leading provider of research tools for the life science industry, since January 2003. From August 2001 to January 2003, Mr. Radak was an independent consultant for various companies. Mr. Radak also served as Vice President of Finance and Corporate Controller for Sunrise Medical Inc. from December 1994 to August 2001. Mr. Radak received his B.A. in Business Administration from California State University, Fullerton and is a Certified Public Accountant.

Richard C. Tarbox, 56, became our Senior Vice President, Corporate Development Officer on July 16, 2007. Prior to joining us, Mr. Tarbox served as Vice President, Strategic Sourcing & Business Development for the Healthcare Market Division of Thermo Fisher Scientific Incorporated, a company focused on meeting diagnostic testing needs in healthcare facilities, since 2004. Prior to Thermo Fisher Scientific and from 1995 to 2003, Mr. Tarbox served as managing partner and founder of The Tarbox Group, L.P., providing management consulting services and investigation and evaluation of private equity investment opportunities. From 1992 to 1995, Mr. Tarbox served as Executive Vice President and

Chief Operating Officer of Ostex International, Inc., a developer and manufacturer of diagnostic products for osteoporosis and other bone health diseases. In addition, from 1981 to 1992, Mr. Tarbox held various senior business development, sales and operations positions with American Hospital Supply Corp/Baxter International, Inc., a global medical products and services company. Mr. Tarbox is a graduate of the University of Washington where he received his Bachelor's Degree in Clinical Psychology and the Kellogg School of Management at Northwestern University where he earned a Master's in Business Management.

Thomas J. Foley, Ph.D., 68, has been our Chief Technology Officer since November 2004. Dr. Foley was Senior Vice President of Research and Development and Regulatory Affairs at Lifepoint Inc., a clinical diagnostics company, from 1998 to 2004. Prior to 1998, he was Executive Vice President of Research and Development with HiChem/Elan Diagnostics from 1994 to 1997. From 1987 to 1994, Dr. Foley was Vice President of Research and Development at Hycor Biomedical, Inc., a company involved in developing reagents and controls for urinalysis, therapeutic drug monitoring and allergy and autoimmune disease states. Dr. Foley was Vice President of Research and Development at Gilford Instruments from 1983 to 1986 and Worthington Diagnostics from 1981 to 1983. In addition, Dr. Foley was Manager of Research and Development at Beckman Instruments from 1979 to 1981. Dr. Foley has a Bachelor of Science and a Ph.D. in Biochemistry from Trinity College, Dublin.

Robert J. Bujarski, J.D., 39, has been our Senior Vice President, General Counsel and Corporate Secretary since March 2007. 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.

Scot M. McLeod, 43, has been our Senior Vice President, Operations since July 2, 2007. Mr. McLeod previously served as the Company's Vice-President, Operations since 2001. Mr. McLeod first joined the Company in 1997 as Director of Production and has held various management operations positions with the Company throughout his ten 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 in OUS/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.

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, 2007, total revenue increased 11% to $118.1 million from $106.0 million for the year ended December 31, 2006. 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.

Our sales estimates for future periods are based on estimated end-user demand for our products. Sales to our distribution partners would fall short of expectations if distributor inventories increase because of less than estimated end-user consumption.

Other 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 a potential influenza pandemic and the related potential impact on humans from avian flu, including the uncertainty surrounding the detection of novel influenza viruses in human specimens and the U.S. Government's recent report which focused on vaccination solutions and called for the development of new rapid diagnostic tests, which are not commercially available at this time, that identify specific strains of influenza and have greater sensitivity and specificity;

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, reduced consumer demand, inflation and currency fluctuations;

changes in sales levels, since a significant portion of our costs are fixed costs with the result that relatively higher sales could likely increase profitability but relatively lower sales would not reduce costs by the same proportion, and hence could cause operating losses;

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

significant quantities of our product in our distributors' inventories or distribution channels; and

changes in distributor buying patterns.

To remain competitive, we must continue to develop or obtain proprietary technology rights; otherwise, other companies may increase their market share by selling technologically superior products that compete with our products.

Our competitive position is heavily dependent on obtaining and protecting our own proprietary technology or obtaining licenses from others. 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 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 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 2024. Additionally, we have patent applications pending throughout the world. 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 protection against competitors with similar technology. Moreover, any patents issued to us may be challenged, invalidated or circumvented in the future. In addition to the U.S., we have patents issued in various other countries including, for example, 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 and might not be able to enforce the license restrictions in a cost-effective manner. Also, we may not be able to obtain licenses for technology patented by others and required to produce our products on commercially reasonable terms.

In order to remain competitive and profitable, we must expend considerable resources to research new technologies and products and develop new markets. Our failure to successfully introduce new technologies and products and develop new markets could have a material adverse effect on our business and prospects.

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 commercially viable, including, without limitation, our strategic efforts relating to: (i) our next generation immunochemical fecal occult blood test, (ii) developing and expanding our molecular diagnostics research and development capabilities, (iii) identifying and commercializing new or higher value lateral flow products, and (iv) identifying and commercializing new markers and products in bone health.

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:

provide clinicians with validated, evidence-based proof which encompasses the clinical efficacy and economic efficiency of our rapid POC tests for the professional market. In conjunction with our QVB commitment, we expect to present ongoing information that supports the adoption of rapid POC testing;

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

drive growth by establishing dedicated distributor partnerships with aggressive performance metrics and expanding our sales organization to assure physician and laboratorian satisfaction through direct relationships with Integrated Delivery Networks and hospitals;

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

as healthcare management continues to move closer to the patient, develop test formats which meet the rigorous requirements for over-the-counter test performance;

continue creation of strong global alliances to assure leadership in key markets;

drive profit through further refinement of our manufacturing efficiencies and productivity improvements, with continued focus on profitable products and markets and our effort to create exceptional competency in new product development process management;

continue to focus our research and development efforts on three areas: 1) new proprietary product platform development, 2) the creation of improved products and new products for existing markets, and 3) products developed under collaborations with other companies for new and existing markets; and

identify and commercialize new markers, products and collaborations in bone health through the SPG. We believe we can capitalize upon our existing microwell plate platform core competencies and long-standing collaborations with key researchers worldwide, which may assist with identifying, developing and producing unique diagnostic and research products targeted at disease state mastery. We characterize this direction as a dedicated focus on Research to Rapids . These assays and reagents may be used by customers throughout the continuum-of-care in the diagnosis of disease and monitoring of therapy to the development of novel therapeutics.

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 the foregoing 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 cut, and by how much. Similarly, if adequate financial, personnel, equipment or other resources are not available, we may be required to delay or scale back our strategic efforts. Our operations will be adversely affected if our total revenue and gross profits do not correspondingly increase or if our technology, product and market development efforts are unsuccessful or delayed. Furthermore, our failure to successfully introduce new 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 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 group of these distributors. Four of our distributors, which are considered to be among the market leaders, collectively accounted for approximately 52%, 59% and 63% of our total revenue for the years ended December 31, 2007, 2006 and 2005, respectively. Even though our distributor mix will likely change from period to period in the future, Cardinal, DS Pharma, NDC and PSS have historically accounted for a significant portion of our total revenue. In addition, we rely on a few key distributors for a majority of our international sales, and will continue to do so for the foreseeable future, including our recently announced agreement in January 2008 with bioMerieux. 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 may pose challenges in our industry's competitive environment, and another suitable distributor may not be found on satisfactory terms. 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.

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 seek licenses from third parties, and materially adversely affect our operating results. In addition, the defense of such claims could result in significant costs and divert the attention of our management and other key employees.

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

Moreover, in the past we have been engaged in litigation with parties that claim, among other matters, that we infringed their patents. 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 which 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 in such litigation 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:

- the pendency of any 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 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.

In addition to the foregoing, we may also 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 party's proprietary rights. Further, our products may contain technology provided to us by other parties such as contractors, suppliers or customers. We may have little or no ability to determine in advance whether such technology infringes the intellectual property rights of a third party. Our contractors, suppliers and licensors may not be required or financially able to indemnify us in the event that a claim of

infringement is asserted against us, or they may be required to indemnify us only up to a maximum amount, above which we would be responsible for any further costs or damages.

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

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 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 we have budgeted for, our total revenue will not grow as much as we hope and the costs we 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 or save time, 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.

Intense competition with other manufacturers of POC diagnostic products may reduce our sales.

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. We also face competition from our distributors since 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, IMA, Beckman, Fisher, Genzyme and Becton. 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 acquire market share from our products through more effective marketing or competitive pricing, our total revenue and profits could be materially and adversely affected. Competition also has the effect of limiting the prices we can charge for our products.

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, our estimates as to 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 that 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 approval can be a lengthy, expensive and uncertain process, making the timing and costs of 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 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 any limitation on our ability to manufacture and market our products could have a material adverse effect on our business.

We are subject to numerous government regulations in addition to FDA regulation, and compliance with changes could increase our costs.

In addition to FDA and other regulations described previously, 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 change or laws regulating any of our businesses are added, the costs of compliance with these laws could substantially increase. Compliance with any future modifications of these laws or 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. To the extent the costs and procedures associated with meeting new 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, including but not limited to chemicals and biological materials such as dimethyl sulfate, sodium nitrite, acetaldehyde, acrylamide, potassium bromate and radionuclides. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. These regulations include federal statutes popularly 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, these future environmental regulations could impair our research, development or production efforts by imposing additional, and possibly substantial, costs on our business. In addition, because of the nature of the penalties provided for in some of these environmental regulations, we could be required to pay sizeable fines, penalties or damages in the event of noncompliance with environmental laws. Any environmental violation or remediation requirement could also partially or completely shut down our research and manufacturing facilities and operations, which would have a material adverse effect on our business. The risk of accidental contamination or injury from these hazardous materials cannot be completely eliminated and exposure of individuals to these materials could result in substantial fines, penalties or damages that are not covered by insurance.

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

The end-users of our products are primarily physicians and other healthcare providers. Use of our products would be adversely impacted if physicians do not receive adequate reimbursement for the cost of our products by their patients' healthcare insurers or payers. Our total revenue could also be adversely affected by changes or trends in reimbursement policies of these governmental or private healthcare payers. 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. 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 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, current demand for our products could require us to spend considerable resources to meet the demand or harm our customer relationships if we are unable to meet demand.

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 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 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 some 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 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 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.

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 one or more of our products proves to be defective, we could be subject to claims of liability that could adversely affect our business.

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 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 profits.

Claims may be made against us 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, if we are held liable, 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 and profitability.

If we are not able to manage our growth strategy or if we experience difficulties integrating companies or technologies we may acquire after the acquisition, our earnings may be adversely affected.

Our business strategy contemplates further growth in the scope of operating and financial systems and the geographical area of our operations, including further expansion outside the U.S., as new products are developed and commercialized or new geographical markets are entered. We may experience difficulties integrating the operations of 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. Should we encounter difficulties in managing these tasks, our growth strategy may suffer and our total revenue and gross profits could be adversely affected.

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 also in Santa Clara and San Diego, where our headquarters and the majority of 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 identify and hire 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 increase our costs, cause interruptions in our current business operations and stifle our growth opportunities.

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 by channeling products through distributor organizations and sales agents. Sales to foreign customers accounted for 14%, 20%, and 25% of our total revenue for the years ended December 31, 2007, 2006 and 2005, respectively. In January 2008, we entered into an agreement with bioMerieux that, among other matters, appoints bioMerieux as the exclusive distributor of all of our current rapid diagnostic products in all regions except the U.S., Japan and Scandinavia, starting in May 2008. Our international sales are subject to inherent economic, political and regulatory risks, which could increase our operating costs, cause

interruptions in our current business operations and impede our international growth. These foreign risks include, among others:

- compliance with new and changing registration requirements, our inability to benefit from registration for our products inasmuch as registrations may be controlled by a distributor, the difficulty in the transitioning of our product registrations, and tariffs or other barriers as we continue to expand into new countries and geographic regions;

- exposure to currency exchange fluctuations, such as the 12% increase and 6% decrease in value of the Euro and Yen, respectively, against the U.S. dollar for the year ended December 31, 2007;

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

Currently, all 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 and our anticipated foreign operations, as could changes in the general economic conditions in those markets. In order to maintain a competitive price for our products in Europe and Japan, we may have to continue to provide discounts or otherwise effectively reduce our prices, resulting in a lower margin on products sold in these geographical territories. 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 will be fully exposed to exchange rate changes.

Investor confidence and share value 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. 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. 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 Stock

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 stock has been highly volatile and has fluctuated substantially in the past. For example, between December 31, 2005 and December 31, 2007, the closing price of our common stock, as reported by the Nasdaq Global Market, has ranged from a low of $8.14 to a high of $20.84. We expect our common stock to continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- 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 onset, length and severity of the cold and flu seasons;
- media attention focused on a potential influenza pandemic and the related potential impact on humans from avian flu, as well as the uncertainty surrounding the detection of novel influenza viruses in human specimens;
- changes in the level of competition, such as would occur if one of our larger and better financed competitors introduced a new and superior technology or a lower priced product to compete with one of our products;
- changes in economic conditions in our domestic and international markets, such as economic downturns, reduced consumer demand, inflation and currency fluctuations, particularly as we expand into markets outside Japan and Western Europe where economic conditions may differ from those prevailing at given times among developed nations;
- changes in sales levels, since a significant portion of our costs are fixed costs with the result that relatively higher sales could likely increase profitability but relatively lower sales would not reduce costs by the same proportion, and hence could cause operating losses;
- declines in orders from major distributors as a result of lower than expected end-user demand, whether as a result of a light cold and flu season or otherwise;
- lower than anticipated sales of our new products;
- our failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about us by securities analysts or major stockholders;
- additions or departures of our key personnel;
- litigation or threat of litigation;
- sales of our common stock and limited daily trading volume; and

economic and other external factors, disasters or crises.

In addition, the stock market in general, and the Nasdaq Global Market and the market for technology 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 by existing stockholders could depress the market price of our common stock.

Sales of our common stock in the public market, or the perception that such sales could occur, could negatively impact the market price of our common stock. As of December 31, 2007:

- approximately 32.7 million shares of our common stock had been issued in registered offerings and 32.0 million are freely tradable in the public markets; and

- approximately 1.7 million shares of our common stock were issuable upon exercise of outstanding stock options under our various equity incentive plans at a weighted average exercise price of $7.55.

We are unable to estimate the number of shares of our common stock that may actually be resold in the public market since this will depend on the market price for our common stock, the individual circumstances of the sellers and other factors. We also have a number of institutional stockholders that own significant blocks of our common stock. If one or more of these stockholders were to sell large portions of their holdings in a relatively short time, for liquidity or other reasons, the prevailing market price of our common stock could be negatively affected.

Anti-takeover devices may prevent a sale, or changes in the management, of the Company.

We have in place several anti-takeover devices, including a stockholder rights plan, that may have the effect of delaying or preventing a sale, or changes in the management, of the Company. For example, our 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.

We may also issue shares of preferred stock without stockholder approval and on terms that our Board of Directors may determine in the future. The issuance of preferred stock could have the effect of making it more difficult for a third party to acquire a majority of our outstanding stock, and the holders of such preferred stock could have voting, dividend, liquidation and other rights superior to those of holders of our common stock.

We do not pay dividends and this may negatively affect the price of our stock.

We have not paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. The future price of our common stock may be adversely impacted because we have not paid and do not anticipate paying dividends.

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 78,000 square-foot facility. The San Diego lease expires in 2014 with options to extend the lease for two additional five-year periods. In addition, 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 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.

Item 4. Submission of Matters to a Vote of Security Holders

There were no matters submitted to a vote of security holders during the fourth quarter of 2007.

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 closing prices for our common stock for the periods indicated.

Quarter Ended	Low	High
December 31, 2007	$ 17.71	$ 20.84
September 30, 2007	13.57	19.56
June 30, 2007	12.18	17.56
March 31, 2007	10.20	13.96
December 31, 2006	$ 13.44	$ 15.81
September 30, 2006	8.14	13.83
June 30, 2006	8.88	13.00
March 31, 2006	9.11	12.82

No cash dividends were declared for our common stock during the fiscal years ended in 2007 or 2006, and we do not anticipate paying any dividends in the foreseeable future. As of February 20, 2008, we had approximately 564 common stockholders of record.

Stock Repurchases

The table below sets forth information regarding repurchases of our common stock by us during the three months ended December 31, 2007. There were no repurchases of equity securities under our previously announced stock repurchase program during the fourth quarter of 2007.

	Total number of shares purchased(1)	Average price paid per share	Total number of shares purchased as part of publicly announced program	Approximate dollar value of shares that may yet be purchased under the program(2)
October 1 - October 31, 2007		$		$ 21,445,000
November 1 - November 30, 2007				21,445,000
December 1 - December 31, 2007	192	18.23		21,445,000
Ending Balance - December 31, 2007	192	$ 18.23	2,776,038	$ 21,445,000

(1) In addition to and apart from our stock repurchase program described below, 192 shares of common stock were repurchased by us in connection with payment of minimum tax withholding obligations relating to the lapse of restrictions on certain restricted stock awards during the three months ended December 31, 2007.

(2) 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 purchase 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 no later than March 9, 2009 unless extended by our Board of Directors.

Equity Compensation Plan Information

Information regarding our equity compensation plans is set forth in the section titled "Equity Compensation Plan Information" in our 2008 Proxy Statement to be filed with the SEC no later than April 29, 2008.

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, 2002 and ending December 31, 2007. The graph assumes an initial investment of $100 on December 31, 2002 in our common stock, the Nasdaq Composite Index and the Nasdaq Pharmaceutical Index and reinvestment of dividends. The stock price performance of our common stock depicted in the graph represents past performance only and is not necessarily indicative of future performance.

Comparison Of Five Year Cumulative Total Return*

Among Quidel Corporation, The NASDAQ Composite Index

And The NASDAQ Pharmaceutical Index

Company/Index	Base Period 12/31/02	12/31/03	12/31/04	12/31/05	12/31/06	12/31/07
Quidel Corporation	**$ 100.00**	$ 310.46	$ 146.44	$ 310.18	$ 392.62	$ 561.26
Nasdaq Composite	**100.00**	149.75	164.64	168.60	187.83	205.22
Nasdaq Pharmaceutical	**100.00**	144.89	160.46	160.65	163.42	154.46

*

$100 invested on 12/31/02 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

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,				
	2007	2006	2005(1)	2004	2003(2)
	(in thousands, except per share data)				
Total revenues	$ 118,065	$ 106,015	$ 92,299	$ 78,691	$ 92,463
Costs and expenses					
Cost of sales (excludes amortization of intangible assets)	48,573	44,818	37,101	35,234	40,943
Research and development	12,855	13,047	12,829	11,340	8,465
Sales and marketing	18,491	16,966	16,121	13,990	15,977
General and administrative	13,167	12,770	13,062	14,852	10,003
Amortization of intangible assets	5,493	4,580	1,476	1,459	1,517
Patent litigation settlement			17,000		
Restructuring					1,966
Total costs and expenses	98,579	92,181	97,589	76,875	78,871
Operating income (loss)	19,486	13,834	(5,290)	1,816	13,592
Other income (expense)					
Interest income	1,891	1,408	722	398	154
Interest expense	(736)	(757)	(808)	(886)	(980)
Other income (expense)	(117)	545	49	256	253
Total other income (expense)	1,038	1,196	(37)	(232)	(573)
Income (loss) from continuing operations before provision (benefit) for income taxes	20,524	15,030	(5,327)	1,584	13,019
Provision (benefit) for income taxes	6,893	(5,891)	3,000		(8,315)
Income (loss) from continuing operations	13,631	20,921	(8,327)	1,584	21,334
Gain (loss) from discontinued operations, net of taxes		797	(932)	(7,871)	(1,683)
Net income (loss)	$ 13,631	$ 21,718	$ (9,259)	$ (6,287)	$ 19,651
Basic earnings (loss) per share:					
Continuing operations	$ 0.43	$ 0.63	$ (0.26)	$ 0.05	$ 0.73
Discontinued operations	0.00	0.02	(0.03)	(0.25)	(0.06)
Net income (loss)	0.43	0.66	(0.28)	(0.20)	0.67
Diluted earnings (loss) per share:					
Continuing operations	$ 0.41	$ 0.61	$ (0.26)	$ 0.05	$ 0.70
Discontinued operations	0.00	0.02	(0.03)	(0.25)	(0.06)
Net income (loss)	0.41	0.63	(0.28)	(0.20)	0.65
Shares used in basic per share calculation	32,028	32,985	32,525	31,487	29,177
Shares used in diluted per share calculation	32,996	34,367	32,525	31,487	30,374

Balance Sheet Data

	December 31				
	2007	2006	2005(1)	2004	2003(2)
	(in thousands)				
Cash and cash equivalents	$ 45,489	$ 36,625	$ 34,930	$ 36,322	$ 25,627
Working capital	$ 70,259	$ 53,063	$ 43,984	$ 49,769	$ 49,529
Total assets	$ 133,838	$ 127,048	$ 113,848	$ 112,691	$ 117,249
Long-term obligations	$ 9,161	$ 9,166	$ 9,986	$ 10,780	$ 11,258
Stockholders' equity	$ 107,703	$ 103,276	$ 87,243	$ 90,185	$ 89,780
Common shares outstanding	32,706	33,530	33,778	31,848	30,406

(1) During the second quarter of 2005, we entered into an agreement to settle certain patent litigation. In conjunction with the settlement, we recorded a charge of $17.0 million in the first quarter of 2005, which amount was paid in April 2005.

(2) This period has been restated for the impact of discontinued operations, which occurred during the fourth quarter of 2004.

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

The following discussion of our financial condition and results of operation 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 operation 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.

Executive Summary

We have a leadership position in the development, manufacturing and marketing of rapid diagnostic solutions at the point-of-care ("POC") in infectious diseases and reproductive and women's health. We focus on POC testing solutions specifically developed for the physician office lab ("POL") and acute care markets globally. We primarily earn revenue from sales of products for use in physician offices, hospitals, clinical laboratories, retail clinics and wellness screening centers. We market our products in the U.S. through a network of national and regional distributors, supported by a direct sales force. Internationally, we sell and market primarily in Japan and Europe by channeling products through distributor organizations and sales agents. Starting in May 2008, bioMerieux S.A. ("bioMerieux") will become our exclusive distributor for all of our current QuickVue® rapid diagnostic tests in all regions except the U.S., Japan and Scandinavia.

A majority of our total revenues relate to three product families. For the years ended December 31, 2007, 2006 and 2005, we derived approximately 81%, 82% and 78%, respectively, of our total revenues from sales of our influenza, Group A Strep and pregnancy tests. Additionally, a significant portion of our total revenue are from a relatively small number of distributors. Approximately 52%, 59% and 63% of our total revenue for the years ended December 31, 2007, 2006 and 2005, respectively, were related to sales through our four largest distributors in each of those periods.

We also develop research products through our Specialty Products Group (the "SPG") with an emphasis on potential future rapid test applications. The SPG is currently responsible for more than 100 of our clinical and research products used worldwide in reference laboratories and in research applications at leading universities and biotechnology companies. The SPG revenues, income and assets are less than 10% of our overall operations.

Our net revenue increased to $118.1 million for the year ended December 31, 2007 from $106.0 million for the year ended December 31, 2006. This was largely driven by increased domestic sales of our infectious disease and reproductive and women's health products as we continued to focus our efforts to strengthen market and brand leadership in infectious disease and reproductive and women's health by delivering economic and clinical proof through our efforts with our Quidel Value Build ("QVB ") program. Our POC testing solutions are designed to provide specialized results that meet two important value criteria that we have branded as QVB :

Clinical validation: the enabling of rapid patient management decisions leading to improved treatment and outcomes.

Economic validation: the reduction of overall costs associated with patient testing with emphasis upon critical reimbursement and payer performance criteria.

We focus on ensuring market leadership and providing points of differentiation by specializing in the diagnosis and monitoring of selected disease states. In order to support our value proposition as a company that markets the highest quality products in support of better medical outcomes, we are highlighting our QVB through the development of new innovations and the communication of new

solutions in the field of rapid diagnostic testing. Our QVB includes significant work in understanding the needs of the end-use customer, building products that meet those needs, providing proof studies to validate rapid diagnostic testing at the point-of-care and leveraging the work of researchers and key opinion leaders studying our tests and technology to help enhance the health and well being of people around the globe. Our marketing strategy includes ensuring each of our key product portfolios is supported by economic and clinical validation that shows hospitals, acute care facilities and POC clinicians that these tests deliver high quality results in a cost-effective manner.

We believe that the trend among healthcare providers to adopt POC testing continues to increase, and demographic changes, reimbursement policies, a shortage of skilled laboratory workers and the availability of clinically valuable tests will increase growth in this diagnostic category. More and more employers, health plans and payers are recognizing that POC testing is a cost-effective means for improving the quality of care and patient satisfaction. Continuous improvements in technologies are resulting in a growing number of new diagnostic tests that combine high levels of accuracy with rapid, easy-to-use product formats. It is our mission to further establish our significant leadership position in POC rapid diagnostics. In order to accomplish this mission, our strategy is to:

provide clinicians with validated, evidence-based proof which encompasses the clinical efficacy and economic efficiency of our rapid POC tests for the professional market. In conjunction with our QVB commitment, we expect to present ongoing information that supports the adoption of rapid POC testing;

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

drive growth by establishing dedicated distributor partnerships with aggressive performance metrics and expanding our sales organization to assure physician and laboratorian satisfaction through direct relationships with Integrated Delivery Networks and hospitals;

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

as healthcare management continues to move closer to the patient, develop test formats which meet the rigorous requirements for over-the-counter test performance;

continue creation of strong global alliances to assure leadership in key markets;

drive profit through further refinement of our manufacturing efficiencies and productivity improvements, with continued focus on profitable products and markets and our effort to create exceptional competency in new product development process management;

continue to focus our research and development efforts on three areas: 1) new proprietary product platform development, 2) the creation of improved products and new products for existing markets, and 3) products developed under collaborations with other companies for new and existing markets; and

identify and commercialize new markers, products and collaborations in bone health through the SPG. We believe we can capitalize upon our existing microwell plate platform core competencies and long-standing collaborations with key researchers worldwide, which may assist with identifying, developing and producing unique diagnostic and research products targeted at disease state mastery. We characterize this direction as a dedicated focus on Research to Rapids . These assays and reagents may be used by customers throughout the continuum-of-care in the diagnosis of disease and monitoring of therapy to the development of novel therapeutics.

As a business in a highly regulated and competitive industry, we face many risks and challenges and we also have opportunities. There are many economic and industry factors that affect our business; some of the more important factors are outlined below:

- sales of our infectious disease products, which have collectively accounted for approximately 64%, 65% and 59% of total revenue for the years ended December 31, 2007, 2006 and 2005, respectively, are subject to and significantly affected by the seasonal demands of the cold and flu seasons;

- sales of our products can be affected significantly by many competitive factors, including convenience, price and product performance as well as the distribution, advertising, promotion and brand name recognition of the marketer;

- intellectual property protection of our products is crucial to our business;

- 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;

- the production processes for POC tests are complex, highly regulated and vary widely from product to product;

- to successfully compete for business in our industry, we believe our POC testing solutions must be designed to provide specific results for clinical and economic validation; and

- there has been a trend toward industry consolidation in our markets over the last several years.

We have entered into an agreement to form a long-term global alliance with bioMerieux in the area of rapid clinical diagnostics for the point-of-care. Starting in May 2008, bioMerieux will become our primary distributor for our current QuickVue® rapid diagnostic tests in all regions except the U.S., Japan and Scandinavia.

In September 2007, we entered an exclusive partnership to provide Roche Pharma AG with the QuickVue® Influenza A+B rapid diagnostic test for marketing activities related to its Tamiflu® (Oseltamivir) antiviral drug for the 2007-2008 influenza season in Germany. The agreement will leverage the strength and speed of the QuickVue® rapid test to help characterize influenza infection along with the Tamiflu® treatment to improve patient recovery time. Subsequently, we also launched a pilot program with Roche in the U.S. for the 2007-08 flu season, which complements the collaboration already underway in Germany.

Outlook

For fiscal year 2008, we anticipate continued year-over-year revenue growth in our infectious disease and reproductive and women's health product lines. We expect gross margins will continue to be positively affected by a more favorable product and geographical mix, increased unit volumes and to a lesser extent increased average selling prices. While we experienced significant year-over-year growth of our immunoassay fecal occult blood test ("iFOB") in 2007, we continue to expect a gradual conversion of the fecal occult blood test market from the current guaiac-based test to an immunochemical-based test. Successful conversion of this market requires changing physician behavior through education, focused in part on clinical and economic validation. Additionally, we expect our respiratory syncytial virus ("RSV") product to be a well-received companion test to our QuickVue® Influenza test so that physicians are well prepared to diagnose and appropriately manage patients with influenza and/or RSV. We received Clinical Laboratory Improvement Amendments of 1988 ("CLIA") waiver on our RSV test in February 2008. Internationally, we expect our global alliance with bioMerieux to increase the reach of our products to markets around the world. Over recent historical

periods, the company has grown operating expenses at a rate less than our revenue growth rate, and we expect this to continue for fiscal 2008.

You should also 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.

Results of Operations

Comparison of years ended December 31, 2007 and 2006

Total Revenues

The following table compares total revenues for the years ended December 31, 2007 and 2006 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2007	2006	$	%
Net product sales	$ 116,890	$ 104,732	$ 12,158	12%
Royalty income and license fees	1,175	1,283	(108)	(8)%
Total revenues	$ 118,065	$ 106,015	$ 12,050	11%

The increase was largely driven by an increase in sales of our infectious disease and reproductive and women's health products of $7.3 million and $2.4 million, respectively. The overall increase was partially offset by an expected decrease of our influenza product revenues in our Japanese market. We believe the increase in total revenue from these product groups was due to successes related to our QVB programs, which have resulted in strengthened customer relationships and preferred partnership programs. We believe that sales of our influenza products continue to increase as a result of increased market awareness, greater utilization and the demonstrated quality of our test. We believe our average selling price in the U.S. has continued to increase largely as a result of our clinical proof claims and product quality, while we have experienced downward pressure in the Japanese market as a result of reimbursement changes and increased competition. Sales of our infectious disease and reproductive and women's health products accounted for 88% and 89% of our total revenue for the years ended December 31, 2007 and 2006, respectively.

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

Cost of Sales

Cost of sales increased 8% to $48.6 million, or 41% of total revenue, for the year ended December 31, 2007 compared to $44.8 million, or 42% of total revenues, for the year ended December 31, 2006. The absolute dollar increase was primarily related to the increase in direct costs (material and labor) associated with the 11% increase in total revenues. The percentage decrease in cost of sales to revenue was primarily due to a more favorable product and geographic mix and the leveraging of fixed costs associated with higher unit volume and increased average selling prices.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2007 and 2006 (in thousands, except percentages):

	For the year ended December 31,					
	2007		2006		Increase (decrease)	
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues	$	%
Research and development	$ 12,855	11%	$ 13,047	12%	$ (192)	(1)%
Sales and marketing	18,491	16%	16,966	16%	1,525	9%
General and administrative	13,167	11%	12,770	12%	397	3%
Amortization of intangible assets	5,493	5%	4,580	4%	913	20%

Research and Development Expense

Our research and development expenses were relatively constant. While we may experience some fluctuation in our research and development activities associated with the timing of certain projects, the primary components of research and development expense are personnel and material costs associated with development of potential new technologies and processes and with products under development. In addition, we continue to incur costs related to intellectual property, clinical activity as well as our overall efforts under our QVB programs.

Sales and Marketing Expense

The increase in sales and marketing expense was primarily related to an overall increase in sales personnel and related programs and expenses, which support our leadership position and strategies to capitalize further on opportunities in POC diagnostics. Other key components of this expense relate to continued investment in assessing future product extensions and enhancements, market research (including voice of customer surveys), programs aimed at distribution partners and end-user customers and reimbursement-related activities and product shipment costs.

General and Administrative Expense

The increase in general and administrative expenses was primary driven by increased stock compensation expense and costs associated with the departure of our former Chief Financial Officer and hiring a new Chief Financial Officer.

Amortization of Intangible Assets

The increase in the amortization of intangible assets was primarily due to a license agreement entered into during late 2006 and an additional license agreement entered into during 2007.

Other Income (Expense)

Interest income was $1.9 million and $1.4 million for the years ended December 31, 2007 and 2006, respectively. The increase in interest income was largely related to the increase in our average cash balance as well as more favorable interest rates for the year ended December 31, 2007 as compared to the prior year. Interest expense was relatively constant at $0.7 million for both of the years ended December 31, 2007 and 2006. Interest expense relates to interest paid on obligations under capital leases, primarily associated with our San Diego facility.

Income Taxes

We recognized income tax expense of $6.9 million for the year ended December 31, 2007 versus a tax benefit of $5.9 million for the year ended December 31, 2006. Income tax expense for 2007 includes a reduction of $0.7 million for the completion of a research and development tax credit study for prior years. For 2006, we recorded a tax benefit which was primarily related to a decrease in the deferred tax valuation allowance during the fourth quarter ended December 31, 2006 and recognizes the deferred tax asset amount considered by management, more likely than not, to be realized.

Comparison of years ended December 31, 2006 and 2005

Total Revenues

The following table compares total revenues for the years ended December 31, 2006 and 2005 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2006	2005	$	%
Net product sales	$ 104,732	$ 88,731	$ 16,001	18%
Research contracts, license fees and royalty income	1,283	3,568	(2,285)	(64)%
Total revenues	$ 106,015	$ 92,299	$ 13,716	15%

The increase in total revenue was largely driven by an increase in sales of our infectious disease products of $14.3 million. The overall increase was partially offset by a decrease of influenza product revenues in our Japanese market. For the year ended December 31, 2006, we believe revenue from these products continued to increase due to successes related to our QVB programs, which have resulted in strengthened customer relationships and preferred partnership programs. We believe that sales of our infectious disease products continued to increase as a result of increased market awareness and the demonstrated quality of our test. We believe our average selling price in the U.S. continued to increase largely as a result of our clinical proof claims and product quality, while we experienced downward pressure in the Japanese market as a result of reimbursement changes and increased competition. This product line collectively accounted for 65% and 59% of our total revenue for the years ended December 31, 2006 and 2005, respectively.

Research Contracts, License Fees and Royalty Income

The decrease for the year ended December 31, 2006 was primarily related to research contract revenue that we earned during the year ended December 31, 2005 in connection with achieving certain milestones under a joint development agreement with another company. During the second quarter of 2005, the joint development agreement was terminated. The balance of this revenue for all periods primarily relates to royalty payments earned on patented technologies of ours utilized by third parties.

Cost of Sales

Cost of sales increased 21% to $44.8 million, or 42% of total revenue for the year ended December 31, 2006 compared to $37.1 million, or 40% of total revenues for the year ended December 31, 2005. The absolute dollar increase was primarily related to the increase in direct costs (material and labor) associated with the 15% increase in total revenues. The percentage increase in cost of sales to revenue was primarily due to the 8.5% royalty we began paying on the majority of our products during the second quarter of 2005 related to the patent litigation settlement with Inverness Medical Innovations, Inc. ("IMA") and strategic investments in our operational infrastructure, partially

offset by a more favorable product and geographic mix, higher unit volume and increased average selling prices.

In connection with the patent litigation settlement entered into during the second quarter of 2005, we were required, as of May 2005, to pay an 8.5% royalty on net sales of our current influenza, Group A Strep, pregnancy, H. pylori, mononucleosis, Chlamydia, iFOB, RSV and veterinary products. These product sales accounted for 92% of total revenue for the year ended December 31, 2006 and 88% for the year ended December 31, 2005. Also for the year ended December 31, 2006, the cost of sales as a percentage of total revenues was favorably impacted compared to 2005 as we fulfilled the terms of an agreement with another party related to the development of our influenza product during the first quarter of 2005. We are no longer required to pay this party a 6% royalty on sales of our influenza product.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2006 and 2005 (in thousands, except percentages):

	For the year ended December 31,					
	2006		2005		Increase (decrease)	
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues	$	%
Research and development	$ 13,047	12%	$ 12,829	14%	$ 218	2%
Sales and marketing	16,966	16%	16,121	17%	845	5%
General and administrative	12,770	12%	13,062	14%	(292)	(2)%
Amortization of intangible assets	4,580	4%	1,476	2%	3,104	210%

Research and Development Expense

Our research and development expenses were relatively constant. The primary components of this expense are personnel and material costs associated with development of potential new technologies and processes and with products under development. In addition, we continued to incur substantial costs related to clinical trials as well as our overall effort under our QVB programs.

Sales and Marketing Expense

The primary components of this expense relate to continued investment in assessing future product extensions and enhancements, market research (including voice of customer surveys), programs aimed at distribution partners and end-user customers and reimbursement-related activities and product shipment costs. We also increased our sales force to further support our leadership position and seek to take advantage of further opportunities in POC diagnostics.

General and Administrative Expense

The decrease in general and administrative expenses for the year ended December 31, 2006 was primarily due to decreased legal fees of $2.3 million associated primarily with the settlement of our intellectual property litigation with IMA during 2005, partially offset by increases in personnel costs associated with stock-based compensation and management incentive plans.

Patent Litigation Settlement

As previously disclosed, during the second quarter of 2005 we entered into an agreement to settle certain patent litigation with IMA and recorded a charge of $17.0 million in the first quarter of 2005, which amount was paid in April 2005.

Amortization of Intangible Assets

The increase in amortization of intangible assets for the year ended December 31, 2006 was primarily due to the amortization of intellectual property related to two license agreements entered into during late 2005 and an additional license agreement entered into during late 2006.

Other Income (Expense)

Interest income was $1.4 million and $0.7 million for the years ended December 31, 2006 and 2005, respectively, and relates primarily to interest earned on our cash and cash equivalents balance. Interest expense was $0.8 million for both of the years ended December 31, 2006 and 2005 and relates to interest paid on obligations under capital leases, which are primarily related to our San Diego facility. Other income increased to $0.5 million for the year ended December 31, 2006 from $0.1 million for the year ended December 31, 2005. During the fourth quarter of 2006, we also recognized non-cash income of approximately $0.5 million associated with certain remaining balance sheet credits of a foreign entity which was previously closed.

Income Taxes

We recorded a tax benefit of $5.9 million for the year ended December 31, 2006 versus a tax provision of $3.0 million for the year ended December 31, 2005. This change is due primarily to a decrease in the deferred tax valuation allowance during the fourth quarter ended December 31, 2006 and recognizes the deferred tax asset amount considered by management, more likely than not, to be realized.

Liquidity and Capital Resources

As of December 31, 2007, our principal sources of liquidity consisted of $45.5 million in cash and cash equivalents as well as $30.0 million available to us under our credit facility, as described below. Our working capital as of December 31, 2007 was $70.3 million.

Our operating activities provided $27.3 million of cash for the year ended December 31, 2007. In addition to the impact on cash from net income, we had increases in accounts receivable and accounts payable related to the timing of sales during the fourth quarter of 2007. Inventory was higher as a result of increased production activities for the cold and flu season. Additionally, the increase in accrued payroll was related to an overall increase in our headcount. The increase in other accrued liabilities was primarily related to amounts due under an acquired license and a non-compete agreement.

Our investing activities used $3.8 million during the year ended December 31, 2007. This included $3.1 million for the acquisition of production and scientific equipment and building improvements and $0.6 million for acquisition of intangible assets. We had investments in property, plant and equipment and intangible assets of $1.0 million and $0.6 million, respectively, which have not been paid as of December 31, 2007.

We are currently planning approximately $6.0 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 information technology. We plan to fund these capital

expenditures with cash flow from operations. We do not have any firm purchase commitments with respect to such planned capital expenditures as of the date of filing this report.

Our financing activities used $14.7 million of cash during the year ended December 31, 2007 and were primarily related to the repurchase of approximately 1.6 million shares of stock in the open market at a cost of $17.9 million and payments on obligations under our capital leases related to our building in San Diego of $0.7 million, partially offset by proceeds of $2.8 million received from the issuance of common stock under our equity incentive and our employee stock purchase plans and $1.0 million in tax benefit from exercise and disposition of employee stock options.

We currently have a $30.0 million credit facility (the "Senior Credit Facility"), which matures on June 30, 2009. The Senior Credit Facility bears interest at a rate ranging from 0% to 0.75% plus the lender's prime rate or, at our option, a rate ranging from 0.75% to 1.75% plus the London InterBank Offering Rate. The agreement governing our Senior Credit Facility also contains certain customary covenants restricting our ability to, among other matters, incur additional indebtedness, create liens or other encumbrances, pay dividends or make other restricted payments, make investments, loans and guarantees or sell or otherwise dispose of a substantial portion of assets to, or merge or consolidate with, another entity. The terms of the Senior Credit Facility require us to comply with certain financial covenants, including: a minimum net worth, a maximum ratio of debt drawn under the Senior Credit Facility to earnings before interest, taxes, depreciation and amortization ("EBITDA") and a fixed charge coverage ratio. As of December 31, 2007, we had $30.0 million of availability under the Senior Credit Facility and we were in compliance with all covenants. See Note 2 in the Notes to the Consolidated Financial Statements included in this Annual Report

We also intend to continue evaluation of acquisition and technology licensing candidates. As such, we may need to incur additional debt, or sell additional equity, to successfully complete these transactions. 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. Based on our current cash position and the current assessment of future operating results, we believe that our existing sources of liquidity will be adequate to meet operating needs during the next 12 months and the foreseeable future.

Off-Balance Sheet Arrangements

At December 31, 2007 and 2006, we did not have any other relationships with unconsolidated entities or financial partners, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

Contractual Obligations

Our facilities and certain equipment are leased under noncancelable capital and operating leases. The following is a summary of our contractual obligations (in thousands):

	Payment due by period				
	Total	Less than 1 year	1-3 Years	3-5 Years	More than 5 years
Capital lease obligations(1)	$ 10,439	$ 1,404	$ 2,893	$ 3,010	$ 3,132
Operating lease obligations(2)	5,908	830	1,699	1,716	1,663
Total	$ 16,347	$ 2,234	$ 4,592	$ 4,726	$ 4,795

(1) Reflects obligations on facilities and equipment under capital leases, including current maturities, in place as of December 31, 2007. Future minimum lease payments are included in the table above.

(2) Reflects obligations on facilities and equipment under operating leases in place as of December 31, 2007. In the fourth quarter of 2007, we entered into a new operating lease at our Santa Clara location, including extending the term of the lease through 2014. Future minimum lease payments are included in the table above.

We have entered into various licensing agreements, which require royalty payments based on specified product sales. These agreements, which have anticipated expiration dates through 2019, encompass the majority of our products. Royalty expenses under these licensing agreements, which are charged to cost of sales, collectively totaled $9.4 million, $9.6 million and $7.1 million for the years ended December 31, 2007, 2006 and 2005, 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, restructuring and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be 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:

Stock-Based Compensation

Prior to January 1, 2006, we accounted for our share-based employee and director compensation plans under the measurement and recognition provisions of Accounting Principles Board Opinion No. 25, "*Accounting for Stock Issued to Employees*," and related Interpretations, as permitted by Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 123, "*Accounting for Stock-Based Compensation*." We recorded no share-based employee and director compensation expense for options granted under our 2001 Equity Incentive Plan or its

predecessor plans prior to December 31, 2005, as all options granted under those plans had exercise prices equal to or greater than the fair market value of our common stock on the date of grant. We did not have material compensation expense in connection with our Employee Stock Purchase Plan. In accordance with SFAS No. 123 and SFAS No. 148, "*Accounting for Stock-Based Compensation Transition and Disclosure*," we disclosed our net income (loss) and net earnings (loss) per share as if we had applied the fair value-based method in measuring compensation expense for our share-based incentive programs.

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123(R), "*Share-Based Payment*," using the modified prospective transition method. Under that transition method, compensation expense that we recognize beginning on that date includes: (a) compensation expense for all share-based awards granted prior to, but not yet vested as of December 31, 2005, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and (b) compensation expense for all share-based awards granted on or after January 1, 2006 based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). Results for prior periods have not been restated.

The computation of the expected option life is based on a weighted-average calculation combining the average life of options that have already been exercised and post-vest cancellations with the estimated life of the remaining vested and unexercised options. The expected volatility is based on the historical volatility of our stock. The risk-free interest rate is based on the U.S Treasury yield curve over the expected term of the option. We have never paid any cash dividends on our common stock and we do not anticipate paying any cash dividends in the foreseeable future. Consequently, we use an expected dividend yield of zero in the Black-Scholes option valuation model. The estimated forfeiture rate of our stock options is 12.7% and is based on our historical experience and future expectations.

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. For stock awards granted prior to December 31, 2005, vesting is based on both the service period as well as the achievement of our performance goals. Meeting the performance goals for these awards allows for acceleration of a portion of the stock awards. A majority of the stock awards granted in 2006 and 2007 were performance-based and vesting is tied to achievement of predetermined revenue and/or EBITDA goals. For purposes of measuring compensation expense, the amount of shares ultimately expected to vest is estimated at each reporting date based on management's expectations regarding the relevant performance criteria. The recognition of compensation expense associated with performance-based grants requires judgment in assessing the probability of meeting the performance goals, as well as defined criteria for assessing achievement of the performance related goals. This may result in significant expense recognition in the period in which the performance goals are met or when achievement of the goals is deemed probable or may result in the reversal of previously recognized stock-based compensation expense if the performance criteria are deemed not probable of being met. The cumulative amount of stock-based compensation expense that has been recognized through December 31, 2007 related to stock awards with performance-related vesting criteria for which the performance criteria have not yet been met is $0.8 million. The grant date of the performance-based stock grants takes place when the grant is authorized and the specific achievement goals are communicated. The communication date of the performance goals can impact the valuation and associated expense of the stock awards.

Revenue Recognition

We record revenues primarily from product sales. These revenues are recorded net of rebates and other discounts which are estimated at the time of sale. The rebates and other discounts are largely driven by various customer program offerings, including special pricing agreements, promotions and other volume-based incentives. Revenue from product sales is recorded upon passage of title and risk of loss to the customer. Change in title to the product and recognition of revenue occur upon delivery to the customer when sales terms are free on board ("FOB") destination and at the time of shipment when the sales terms are FOB shipping point and there is no right of return. We also earn income from the licensing of technology and have previously earned income from performing services under a joint development agreement. 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. Milestone payments, arising under joint development agreements, were previously recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone had been achieved, provided that (i) the milestone event was substantive and its achievability was not reasonably assured at the inception of the agreement, and (ii) our performance obligations after the milestone achievement would continue to be funded by the collaborator at a level comparable to before the milestone achievement. If both of these criteria were not met, the milestone payment would be recognized over the remaining minimum period of our performance obligations under the agreement. Income earned from licensing activities is a component of total revenues in the accompanying Consolidated Statements of Operations.

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. On January 1, 2002, we adopted SFAS No. 142 "*Goodwill and Other Intangible Assets*," which requires that goodwill and other intangible assets that have indefinite lives not be amortized but instead be tested at least annually for impairment, or more frequently when events or changes in circumstances indicate that the asset might be impaired. Examples of such events or circumstances include:

the asset's ability to continue to generate income from operations and positive cash flow in future periods;

any volatility or significant decline in our stock price and market capitalization compared to our net book value;

loss of legal ownership or title to an asset;

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

the impact of significant negative industry or economic trends.

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

For indefinite-lived intangible assets, impairment is tested by comparing the carrying value of the asset to the fair value of the reporting unit to which the asset is assigned. 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. SFAS No. 142 requires periodic evaluations for impairment of goodwill balances. We completed our annual evaluation for impairment of goodwill as of December 31, 2007 and determined that no impairment of goodwill existed.

Income Taxes

We account for income taxes in accordance with SFAS No. 109, "*Accounting for 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 is 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.

Effective January 1, 2007, we adopted the provisions of FASB No. 48, "*Accounting for Uncertainty in Income Taxes"* ("FIN 48"). FIN 48 provides guidance for the recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In accordance with FIN 48, we recognized a cumulative-effect adjustment of $0.7 million, increasing the January 1, 2007 balance of retained earnings. See Note 3 in the Notes to the Consolidated Financial Statements included in this Annual Report for more information on income taxes.

As a result of the adoption of SFAS No. 123(R), we will 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, 2007 and 2006, deferred tax assets do not include $7.1 million and $6.0 million, respectively, of these excess tax benefits from employee stock option exercises that are a component of our net operating loss carryforwards. Additional paid-in capital will be increased up to $7.1 million if such excess tax benefits are realized.

We will continue to assess the assumptions used to determine the valuation allowance. Should we determine that we would not be able to realize all or part of the other components of the deferred tax asset in the future, an adjustment to the deferred tax asset would be charged to earnings in the period such determination were made. Conversely, if based on estimates of future earnings, we determined that all or a portion of the valuation allowance is no longer warranted, a reduction in the valuation

would result in a corresponding credit to additional paid-in capital and/or income tax expense in the period such determination were made.

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. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments at December 31, 2007. Based on our market risk sensitive instruments outstanding at December 31, 2007 and 2006, we have determined that there was no material market risk exposure 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, 2007, our cash and cash equivalents were placed in money market or overnight funds that are highly liquid and which we believe are not subject to material market fluctuation risk.

Foreign Currency Exchange Risk

All 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 and our anticipated foreign operations, 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 will be 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, 2007 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 controls over financial reporting during the fourth quarter of 2007 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, 2007.

The effectiveness of our internal control over financial reporting as of December 31, 2007 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included in this Item 9A.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The Board of Directors and
Stockholders of Quidel Corporation

We have audited Quidel Corporation's internal control over financial reporting as of December 31, 2007, 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, 2007, 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 and subsidiaries as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007 of Quidel Corporation and our report dated February 27, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 27, 2008

Item 9B. Other Information

2007 Annual Meeting of Stockholders

The Company's 2008 Annual Meeting of Stockholders will be held on Tuesday, May 13, 2008, beginning at 8:30 a.m. (local time) at 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 2008 Proxy Statement, which will be filed with the SEC no later than April 29, 2008. Information with respect to executive officers is included under Item 1 on pages 13-14 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," "Code of Business Conduct and Ethics" and "Section 16(a) Beneficial Ownership Reporting Compliance," to be contained in our 2008 Proxy Statement, which will be filed with the SEC no later than April 29, 2008.

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 2008 Proxy Statement, which will be filed with the SEC no later than April 29, 2008.

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 "Equity Compensation Plan Information" and "Security Ownership of Certain Beneficial Owners and Management" to be contained in our 2008 Proxy Statement, which will be filed with the SEC no later than April 29, 2008.

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," "Certain Relationships and Related Transactions" and "Director Independence" to be contained in our 2008 Proxy Statement, which will be filed with the SEC no later than April 29, 2008.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated by reference from the information under the caption "Independent Registered Public Accounting Firm" to be contained in our 2008 Proxy Statement, which will be filed with the SEC no later than April 29, 2008.

Part IV

Item 15. Exhibits and Financial Statement Schedules

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

(a)

(1) Financial Statements

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

Consolidated Financial Statements of Quidel Corporation

(2)

Financial Statement Schedules

The following Financial Statement Schedule of Quidel Corporation for the years ended December 31, 2007, 2006 and 2005 is filed as part of this Annual Report and should be read in conjunction with the Consolidated Financial Statements of Quidel Corporation:

Schedule II. Consolidated Valuation and Qualifying Accounts.

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

(3)

Exhibits. See Paragraph 15(b) below.

(b)

Exhibits

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

(c)

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

Not applicable.

SIGNATURES

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

QUIDEL CORPORATION

Date: March 4, 2008

By /s/ CAREN L. MASON

Caren L. Mason
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/ CAREN L. MASON Caren L. Mason	President, Chief Executive Officer (Principal Executive Officer), and Director	March 4, 2008
/s/ JOHN M. RADAK John M. Radak	Chief Financial Officer, (Principal Financial Officer and Accounting Officer)	March 4, 2008
/s/ MARK A. PULIDO Mark A. Pulido	Chairman of the Board	March 4, 2008
/s/ THOMAS D. BROWN Thomas D. Brown	Director	March 4, 2008
/s/ KENNETH F. BUECHLER Kenneth F. Buechler	Director	March 4, 2008
/s/ RODNEY F. DAMMEYER Rodney F. Dammeyer	Director	March 4, 2008
/s/ MARY LAKE POLAN Mary Lake Polan	Director	March 4, 2008
/s/ JACK W. SCHULER Jack W. Schuler	Director	March 4, 2008

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON FINANCIAL STATEMENTS

The Board of Directors and
Stockholders of Quidel Corporation

We have audited the accompanying consolidated balance sheets of Quidel Corporation and subsidiaries as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007. 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 and subsidiaries at December 31, 2007 and 2006, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2007 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.

As discussed in Note 1 to the consolidated financial statements, Quidel Corporation adopted Statement of Financial Accounting Standards No. 123 (revised 2004) on January 1, 2006 and FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109," effective January 1, 2007.

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, 2007, 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 27, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Diego, California
February 27, 2008

QUIDEL CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except par value)

	December 31,	
	2007	**2006**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 45,489	$ 36,625
Accounts receivable, net	23,163	18,139
Inventories	11,037	9,625
Deferred tax asset current	5,955	1,590
Prepaid expenses and other current assets	1,589	1,690
Total current assets	87,233	67,669
Property, plant and equipment, net	19,926	20,058
Intangible assets, net	14,320	18,797
Deferred tax asset non-current	11,923	20,065
Other non-current assets	436	459
Total assets	$ 133,838	$ 127,048
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,618	$ 3,832
Accrued payroll and related expenses	4,341	4,868
Accrued royalties	3,289	3,559
Current portion of obligations under capital leases	764	675
Other current liabilities	2,962	1,672
Total current liabilities	16,974	14,606
Capital leases, net of current portion		