

QUIDEL CORP /DE/  
Form 10-K  
March 14, 2007

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-K

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

For the fiscal year ended December 31, 2006

OR

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

For the transition period from N/A to

Commission file number: 0-10961

## QUIDEL CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)  
10165 McKellar Court  
San Diego, California  
(Address of principal executive offices)

94-2573850  
(I.R.S. Employer  
Identification No.)

92121  
(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  No

## Edgar Filing: QUIDEL CORP /DE/ - Form 10-K

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was \$278,271,815 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 March 7, 2007, 33,052,345 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 2007 Annual Meeting of Stockholders (to be held on May 7, 2007) are incorporated by reference into Part III, Items 10, 11, 12, 13 and 14 of this Annual Report on Form 10-K.

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## A Warning About Forward Looking Statements

This Annual Report on Form 10-K contains forward looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those currently expected. 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 length and severity of cold and flu seasons, 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 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 worldwide leadership position in the development, manufacturing and marketing of rapid diagnostic solutions at the professional point-of-care (POC) in infectious diseases and reproductive health. We focus on POC testing solutions specifically developed for the physician office lab and acute care markets globally. We sell our products to professionals for use in physician offices, hospitals, clinical laboratories 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.

In addition to our rapid 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, earnings and assets are less than 10% of our overall operations.

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.

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](http://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](http://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 establish our significant leadership position in POC rapid diagnostics. In order to accomplish this mission, our strategy is to:

- provide clinicians with validated, value-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;
- pursue over-the-counter opportunities with strategic partners;
- continue to focus on strengthening our market and brand leadership in infectious diseases and reproductive 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 satisfaction;
- 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;
- 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; and

- pursue licensing, acquisition and partnership opportunities that meet our dedicated focus on Research to Rapids .

## **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 \$24.0 billion in 2004, and is segmented by the particular test discipline. The largest segments are immunodiagnosics testing and instrument-based clinical chemistry, which account for approximately 31% and 21% of the total IVD market, respectively. Geographically, approximately 40% of total IVD revenues are generated in the U.S., while Europe, Japan and the rest of the world account for approximately 33%, 14% and 13%, 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 were approximately 125 million visits to emergency departments in 2004, representing an increase of approximately 11% above the 2003 figure.

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 diagnostic parameters has become an accepted adjunct to central laboratory and self-testing. The professional POC market is comprised of two general segments: hospital testing (emergency rooms and bedside) and decentralized testing in non-institutional settings such as physicians' offices. 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 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 \$420 million in 2004 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 2005, an estimated 99,000, or 55%, of physician office laboratories had a CLIA waiver.

## Products

A majority of our net sales relate to three product families. For the years ended December 31, 2006, 2005 and 2004, we derived approximately 83%, 82% and 77%, respectively, of our net sales 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 net sales 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, 2006, 2005 and 2004, export sales to unaffiliated customers constituted approximately 20%, 26% and 29%, respectively, of net sales. The export sales were primarily to customers in Japan and Europe. We expect that export sales will continue to represent a significant portion of our net sales in the foreseeable future.

We provide rapid POC and other diagnostic tests under the following brand names: QuickVue®, QuickVue+®, QuickVue Advance®, RapidVue® 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.

*Mononucleosis.* Infectious Mononucleosis can be severely debilitating to immune suppressed groups, including the elderly, if not diagnosed and treated promptly. Our Quick Vue® Infectious Mononucleosis test is a rapid, qualitative immunoassay for the detection of IgM heterophile antibodies in acute phase infections.

#### *Reproductive Health*

*Pregnancy.* The early detection of pregnancy enables the physician and patient to institute proper care, helping to promote the health of both the woman and the developing embryo. Our QuickVue® pregnancy tests are sensitive immunoassay tests for the qualitative detection of human Chorionic Gonadotropin (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 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. Our Gardnerella Vaginalis test, launched in July 2002, utilizes our Layered Thin Film ( LTF ) technology and tests for infectious vaginitis.

#### *Oncology/Gastrointestinal*

*Immunoassay fecal occult blood test ( iFOB ).* Our QuickVue® iFOB test is a rapid immunochemical diagnostic tool 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 believed to be associated with approximately 80% of those 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 the 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 H. pylori bacterium. Our initial H. pylori test was the first rapid H. pylori test to be granted a CLIA waiver. We launched our second generation CLIA-waived test, QuickVue® H. Pylori gII test in August 2000.

#### *Bone Health*

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





### *Other Products*

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

### **New Products**

- *RSV Test:* Our QuickVue® RSV test is a rapid immunoassay for Respiratory Syncytial 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.

*iFOB Test:* Our QuickVue® iFOB test is a rapid immunochemical diagnostic tool 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.

We believe the potential domestic market opportunities, on a per test basis, are approximately 2 million and 50 million for our RSV and iFOB products, respectively.

### **Seasonality**

Sales of our Group A Strep, influenza and RSV 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, 2006, 2005 and 2004, net sales in the first and fourth quarters have combined for 62%, 63% and 65%, respectively. Historically, our sales of our Group A Strep and influenza products have varied from year to year based in large part on the severity and length of the cold and flu season. For the years ended December 31, 2006, 2005 and 2004, sales of our influenza and Group A Strep products accounted for 64%, 60% and 55%, respectively, of net sales. We began selling our RSV product in late 2006 and had immaterial product sales of our RSV product for the year ended December 31, 2006. 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 and length of the cold and flu season will continue to impact sales of our Group A Strep, RSV, and influenza 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 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 these chosen 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 \$13.0 million, \$12.8 million and \$11.3 million for the years ended December 31, 2006, 2005 and 2004, respectively. Expenses related to customer sponsored research activities for the year ended December 31, 2004 were \$0.6 million. There were no significant customer sponsored research activities during the years ended December 31, 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, 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.

During 2006, 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 extensive VOC emphasis enables us to understand the customer's needs and requirements in both domestic and international markets in order to better 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 2006, we conducted several clinical studies and/or sponsored others that have resulted in abstracts, posters and publications, which included presentations at the American Society of Microbiology and the Infectious Disease Society of America and publications in the *Journal of Clinical Microbiology*.

We derive a significant portion of our net sales from a relatively small number of distributors. Four of our distributors, which are considered to be among the market leaders, collectively accounted for approximately 59%, 62% and 48% of our net sales for the years ended December 31, 2006, 2005 and 2004, 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 net sales. 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 net sales 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, in addition to the ISO 9001 certification, 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 9001 and 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 federal 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 of our products. Although we seek to reduce our dependence on sole or limited source suppliers, 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 two 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.

On September 7, 2005 the FDA issued a new draft guidance entitled Draft Guidance for Industry and FDA Staff. Recommendation for CLIA waiver applications. The new guidance is not yet activated, but we believe its implementation is imminent. The guidance sets forth new requirements for obtaining a CLIA waiver. These requirements are onerous and will increase the time and cost required to obtain a CLIA waiver.

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 in Japan 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 US and internationally, with

expiration dates ranging from the present through approximately 2022 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 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 and/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, 2006, we had 266 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, 2006 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 immediately following the Annual Meeting of Stockholders. 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*, 53, 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*, 46, 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.

*Mark E. Paiz*, 45, has been our Chief Operating Officer since July 2004. From April 2003 to July 2004, he was our Senior Vice President, Technology and Business Development. From September 2002 to March 2003, Mr. Paiz was our Senior Vice President, Supply Chain and Business Development. From March 2001 to September 2002, Mr. Paiz was Senior Vice President, Information Technology and Supply Chain Management. From August 1999 to March 2001, Mr. Paiz was our Senior Vice President, Product Development and Supply Operations. From June 1998 to August 1999, Mr. Paiz was our Vice President, Operations. Mr. Paiz joined us in December 1997 as Senior Director, Manufacturing. From 1995 to 1997, Mr. Paiz served as Director of Research and Development and Project Manager at Medtronic Interventional Vascular. From 1992 to 1995, he served as a manager at Hybritech, Inc. with various responsibilities including quality engineering, materials management, supplier development and inspection. Mr. Paiz received his B.S. degree in Engineering from the University of Colorado and his M.B.A. from West Coast University.

*Thomas J. Foley, Ph.D.*, 67, 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.*, 38, 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.

*Paul E. Landers*, 59, is our Principal Financial and Accounting Officer, and was our Chief Financial Officer from September 2001 through January 2007. We announced Mr. Landers' retirement on September 7, 2006 and his retirement will become effective March 31, 2007. From September 2001 to March 2003, he was our Vice President and Chief Financial Officer. Prior to joining us, Mr. Landers was the Chief Financial Officer and a Director of International Isotopes Inc., a public contract manufacturer of radiopharmaceuticals and radiochemicals for industrial and healthcare applications, from 2000 to 2001. Previously, Mr. Landers was Chief Financial Officer of Aavid Thermalloy LLC, a leading provider of thermal management solutions, from 1994 to 2000. Mr. Landers currently serves as a member of the Board of Directors of Medmarc Mutual Insurance Company. Mr. Landers received his B.A. degree from the University of Massachusetts and his M.B.A. from Boston College.

## **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, 2006, net sales increased 18% to \$104.7 million from \$88.7 million for the year ended December 31, 2005. 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 Group A Strep and influenza 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;

government and media attention focused on 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 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 net sales 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 2022. 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 LTF technology platform and migration of products to that platform, (ii) developing and expanding our molecular diagnostics research and development capabilities, and (iii) identifying and commercializing new markers and products in bone health. For example, if we are unsuccessful with our strategic efforts around the development of our LTF immunoassay technology whether as the result of failure to achieve desired clinical end points, commercial viability or a change in strategic direction, we would have an impairment of our assets. We currently anticipate that we will reach a determination as to our continued investment in our LTF immunoassay technology during 2007. As of December 31, 2006, we have approximately \$8.0 million of net assets related to our LTF technology.

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, value-based proof which encompasses the clinical efficacy and economic efficiency of our rapid POC tests for the professional market;
- pursue over-the-counter opportunities with strategic partners;
- strengthen market and brand leadership in infectious disease and reproductive health;
- drive growth by establishing dedicated distributor partnerships and expanding our sales organization;
- drive profit through further refinement of industry leading manufacturing efficiencies;
- 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;
- develop and maintain key relationships with third parties and cooperative collaborations;
- identify and commercialize new markers, products and collaborations in bone health through our SPG; and
- pursue licensing, acquisition and partnership opportunities that meet our dedicated focus on Research to Rapids .

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 net sales 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 net sales. 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, 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 59%, 62% and 48% of our net sales for the years ended December 31, 2006, 2005 and 2004, 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 net sales. 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 net sales to these or any of our other significant distributors were to decrease in any material amount in the future, our business, operating results and financial condition could be materially and adversely affected.

As an alternative, we could expand our efforts to distribute and market our products directly. This alternative, however, would require substantial investment in additional sales and marketing resources, including hiring additional field sales personnel, which would significantly increase our future selling, general and administrative expenses. If we were to make the substantial investment to directly distribute and market our products and were unsuccessful, our net sales and profits 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 or other key employees.**

Companies in and 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.

For example and as previously disclosed, beginning in February 2004, a number of legal proceedings were initiated by us, IMA and IMA's affiliates in Germany and the U.S. raising, among other items, issues of patent infringement, patent enforceability and patent invalidity relative to fundamental, lateral-flow technology. In legal proceedings in the U.S., in addition to IMA and IMA's affiliates, Church & Dwight was also a party involved in the legal proceedings.

In April 2005, we entered into an agreement with IMA settling all domestic and international actions involving IMA and IMA's affiliates, and we and IMA agreed to cross-license, and to cause our and their affiliates to cross-license, the parties' respective lateral flow patent portfolios. In addition, in March 2006, we settled the pending intellectual property litigation with Church & Dwight and agreed to cross-license certain patents related to lateral flow technology for the over-the-counter market.

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 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/or 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/or 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 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 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 laboratories. Clinical reference laboratories and hospital-based laboratories are significant competitors for our products 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 net sales 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 net sales 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. Regulatory approval can be a lengthy, expensive and uncertain process, making the timing and costs of approvals difficult to predict. Our net sales would be negatively affected by delays in the receipt of, delay if we change, or failure to receive, 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 our costs. 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 as well.

**Our net sales 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 net sales 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 net sales 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 net sales 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 obtain alternative sources for this supply, could have a material adverse effect on our net sales 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. 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 and 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 area of our operations, including further expansion outside the U.S., as new products are developed and commercialized. We may experience difficulties integrating our own operations with those of companies or technologies that we may acquire, 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 net sales 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/or stifle our growth opportunities.**

Our products are sold internationally, primarily 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 20%, 26% and 29% of our net sales for the years ended December 31, 2006, 2005 and 2004, respectively. 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 product, inasmuch as registration may be controlled by a distributor, 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% and 1% decrease in value of the Euro and Yen, respectively, against the U.S. dollar for the year ended December 31, 2006;
- longer payment cycles 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 and/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 and report on management's assessment as well as 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 decline to attest to management's assessment or 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, 2004 and December 31, 2006, the closing price of our common stock, as reported by the Nasdaq Global Market, has ranged from a low of \$3.55 to a high of \$15.81. 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 Group A Strep and influenza 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;
- 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, 2006:

- approximately 33.5 million shares of our common stock had been issued in registered offerings and 32.9 million are freely tradable in the public markets; and
- approximately 2.0 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 \$5.87, for stock options.

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 2009.

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 2006.

**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.

<b>Quarter Ended</b>	<b>Low</b>	<b>High</b>
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
December 31, 2005	\$ 8.88	\$ 15.51
September 30, 2005	5.18	9.71
June 30, 2005	3.55	5.19
March 31, 2005	3.80	5.01

No cash dividends were declared for our common stock during the fiscal years ended in 2006 or 2005, and we do not anticipate paying any dividends in the foreseeable future. There were no repurchases of equity securities under our stock repurchase program during the fourth quarter of 2006. As of March 1, 2007, we had approximately 601 common stockholders of record.

**Stock Repurchase**

The table below sets forth information regarding repurchases of our common stock by us during the three months ended December 31, 2006.

	<b>Total number of shares purchased</b>	<b>Average price paid per share</b>	<b>Total number of shares purchased as part of publicly announced program</b>	<b>Approximate dollar value of shares that may yet be purchased under the program(1)</b>
Beginning Balance - October 1, 2006	1,252,002	\$ 9.20	1,252,002	\$ 13,400,000
October 1 - October 31, 2006				13,400,000
November 1 - November 30, 2006				13,400,000
December 1 - December 31, 2006				13,400,000
Ending Balance - December 31, 2006	1,252,002	\$ 9.20	1,252,002	\$ 13,400,000

(1) In June 2005, we announced that our Board of Directors had authorized us to repurchase up to \$25.0 million in shares of our common stock. 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. In March 2007, our Board of Directors authorized us to repurchase up to an additional \$25 million in shares of our common stock.

In addition to the stock repurchase program noted above, we repurchased 395 shares of common stock, at a cost of \$14.05 per share, in connection with payment of tax withholding obligations relating to the lapse of restrictions on certain restricted stock awards during the three months ended December 31, 2006.

**Equity Compensation Plan Information**

Information regarding our equity compensation plans is set forth in the section titled "Equity Compensation Plan Information" in our 2007 Proxy Statement to be filed with the SEC no later than April 30, 2007.

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**STOCKHOLDER RETURN PERFORMANCE GRAPH**

## Edgar Filing: QUIDEL CORP /DE/ - Form 10-K

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, 2001 and ending December 31, 2006. The graph assumes an initial investment of \$100 on December 31, 2001 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					
	12/31/01	12/31/02	12/31/03	12/31/04	12/31/05	12/31/06
Quidel Corporation	\$ 100.00	\$ 45.11	\$ 140.05	\$ 66.06	\$ 139.92	\$ 177.11
Nasdaq Composite	100.00	69.66	99.71	113.79	114.47	124.20
Nasdaq Pharmaceutical	100.00	64.40	92.31	100.78	113.36	115.84

\* \$100 invested on 12/31/01 in stock or index-including reinvestment of dividends. Fiscal year ending December 31.

\* For purposes of the comparison in the performance graph above, the Company selected the Nasdaq Composite Index in lieu of the Nasdaq Market Index U.S. (which was utilized in the preceding fiscal year) because the Nasdaq Market Index U.S. has been discontinued and is no longer available.

**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,				
	2006	2005(1)	2004	2003(2)	2002(2)
	(in thousands, except per share data)				
<b>REVENUES</b>					
Net sales	\$ 104,732	\$ 88,731	\$ 76,072	\$ 90,866	\$ 71,622
Research contracts, license fees and royalty income	1,283	3,568	2,619	1,597	1,651
Total revenues	106,015	92,299	78,691	92,463	73,273
<b>COSTS AND EXPENSES</b>					
Cost of sales	44,818	37,101	35,234	40,943	35,422
Research and development	13,047	12,829	11,340	8,465	6,748
Sales and marketing	16,966	16,121	13,990	15,977	14,649
General and administrative	12,770	13,062	14,852	10,003	8,845
Patent litigation settlement		17,000			
Amortization of intangibles	4,580	1,476	1,459	1,517	1,405
Restructuring				1,966	
Total costs and expenses	92,181	97,589	76,875	78,871	67,069
Operating earnings (loss)	13,834	(5,290 )	1,816	13,592	6,204
<b>OTHER INCOME (EXPENSE)</b>					
Interest income	1,408	722	398	154	13
Interest expense	(757 )	(808 )	(886 )	(980 )	(960 )
Other income	545	49	256	253	317
Total other income (expense)	1,196	(37 )	(232 )	(573 )	(630 )
Earnings (loss) from continuing operations before (benefit) provision for income taxes	15,030	(5,327 )	1,584	13,019	5,574
(Benefit) provision for income taxes	(5,891 )	3,000		(8,315 )	2,182
Earnings (loss) from continuing operations	20,921	(8,327 )	1,584	21,334	3,392
Gain (loss) from discontinued operations, net of taxes	797	(932 )	(7,871 )	(1,683 )	(2,101 )
Net earnings (loss)	\$ 21,718	\$ (9,259 )	\$ (6,287 )	\$ 19,651	\$ 1,291
<b>Basic earnings (loss) per share:</b>					
Continuing operations	\$ 0.63	\$ (0.26 )	\$ 0.05	\$ 0.73	\$ 0.12
Discontinued operations	0.02	(0.03 )	(0.25 )	(0.06 )	(0.07 )
Net earnings (loss)	0.66	(0.28 )	(0.20 )	0.67	0.04
<b>Diluted earnings (loss) per share:</b>					
Continuing operations	\$ 0.61	\$ (0.26 )	\$ 0.05	\$ 0.70	\$ 0.11
Discontinued operations	0.02	(0.03 )	(0.25 )	(0.06 )	(0.07 )
Net earnings (loss)	0.63	(0.28 )	(0.20 )	0.65	0.04
Shares used in basic per share calculation	32,985	32,525	31,487	29,177	28,824
Shares used in diluted per share calculation	34,367	32,525	32,386	30,374	29,629

**Balance Sheet Data**

	<b>December 31 2006 (in thousands)</b>	<b>2005(1)</b>	<b>2004</b>	<b>2003(2)</b>	<b>2002(2)</b>
Cash and cash equivalents	\$ 36,625	\$ 34,930	\$ 36,322	\$ 25,627	\$ 2,910
Working capital	\$ 53,063	\$ 43,984	\$ 49,769	\$ 49,529	\$ 24,002
Total assets	\$ 127,048	\$ 113,848	\$ 112,691	\$ 117,249	\$ 82,593
Long-term obligations	\$ 9,166	\$ 9,986	\$ 10,780	\$ 11,258	\$ 11,438
Stockholders' equity	\$ 103,276	\$ 87,243	\$ 90,185	\$ 89,780	\$ 62,757
Common shares outstanding	33,530	33,778	31,848	30,406	28,889

(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) These periods have 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 health. We focus on POC testing solutions specifically developed for the physician office lab and acute care markets globally. We primarily earn revenue from sales of products for use in physician offices, hospitals, clinical laboratories 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.

We derive a majority of our net sales from three product lines. For the years ended December 31, 2006, 2005 and 2004, we derived approximately 83%, 82% and 77%, respectively, of our net sales from sales of our influenza, pregnancy and Group A Strep tests. In the U.S., we lead the professional market in these three product categories with an estimated 69%, 48%, and 47% market share in influenza, pregnancy and Group A Strep products, respectively, as of December 31, 2006. The market share data is estimated based on trailing twelve month sales from distribution to end use customers. Additionally, a significant portion of our net sales are from a relatively small number of distributors. Approximately 59%, 62% and 48% of our net sales for the years ended December 31, 2006, 2005 and 2004, respectively, were related to sales through our four largest distributors in each of those periods.

We also develop research products through our 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, earnings and assets are less than 10% of our overall operations.

Our product sales increased to \$104.7 million for the year ended December 31, 2006 from \$88.7 million for the year ended December 31, 2005. This was largely driven by increased domestic sales of our influenza and Group A Strep tests as we continued to focus our efforts to strengthen market and brand leadership in infectious disease and reproductive 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, value-based proof which encompasses the clinical efficacy and economic efficiency of our rapid POC tests for the professional market;
- pursue over-the-counter opportunities with strategic partners;
- strengthen market and brand leadership in infectious disease and reproductive health;
- drive growth by establishing dedicated distributor partnerships and expanding our sales organization;
- drive profit through further refinement of industry leading manufacturing efficiencies;
- 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;
- develop and maintain key relationships with third parties and cooperative collaborations;
- identify and commercialize new markers, products and collaborations in bone health through our SPG; and
- pursue licensing, acquisition and partnership opportunities that meet our dedicated focus on Research to Rapids .

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 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;
- there has been a trend toward industry consolidation in our markets over the last few years; and
- sales of our Group A Strep and influenza products, which have collectively accounted for approximately 64%, 60% and 55% of net sales for the years ended December 31, 2006, 2005 and 2004, respectively, are subject to, and significantly affected by, the seasonal demands of the cold and flu seasons.

During the fourth quarter of 2006, we launched our QuickVue® RSV test upon receiving clearance from the FDA. Our QuickVue® RSV test allows for the rapid, qualitative detection of respiratory syncytial virus directly from nasopharyngeal swab and nasopharyngeal aspirate specimens. This test is intended for use as an aid in the rapid diagnosis of acute RSV viral infections. RSV infection is recognized as the leading cause of hospitalization of children during the first year of life. It is the leading cause of bronchiolitis and pneumonia in infants and small children under two years old, increases an infant's risk of getting an ear infection and may exacerbate asthma or other chronic lung conditions in both children and adults. With seasonality from late fall into the spring and many symptoms similar to those of the common cold and flu, RSV often goes undiagnosed or misdiagnosed, thus increasing the risk of serious health complications. In 2005/2006 clinical studies with nasopharyngeal aspirate specimens, our QuickVue® RSV test correctly identified 99% of the patients infected with RSV and 92% of patients as negative for RSV when compared to cell culture, as well as 92% clinical sensitivity and specificity when using nasopharyngeal swab specimens.

After the initial year of introduction, our QuickVue® IFOB test is gaining momentum. Our test is intended to detect the presence of human blood in stool specimens. Blood in the stool is an indication of a number of gastrointestinal conditions including colorectal cancer. In the FOB market, we have seen an increase in the conversion of guaiac based FOB tests to the newer immunochemical FOB tests. The QuickVue® brand has made progress in three major segments: the physician's office, the acute care and reference labs. Special packaging has been designed and implemented to meet the specific needs of each customer segment. Investment continues in clinical proof as part of our QVB program as well as increased educational efforts to further the conversion by health care professionals. We believe the potential domestic market opportunity is approximately 50 million tests.

In December 2006, we secured an exclusive license for the molecular diagnostic technology in the MChip (a microarray technology) for flu, developed to detect, type and subtype inter pandemic influenza viruses, such as H1N1 and H3N2, and avian influenza viruses, such as H5N1. The MChip technology may be used in conjunction with reverse transcription polymerase chain reaction ( RT-PCR ) to detect, type and subtype specific influenza viruses. The microarray technology is multiplex in nature allowing detection of a broad spectrum of influenza subtypes. We are currently working on the development of our Phase I product targeted for use in influenza surveillance.

We entered into an agreement with a third party during the fourth quarter of 2006 whereby we obtained a sublicense to certain lateral flow technology. Per the terms of the sublicense agreement, we made a one-time payment of \$6.5 million as consideration for the fully paid-up license, and the amount will be amortized ratably through the expiration of the applicable patents in December 2008.

## **Outlook**

For fiscal year 2007, we anticipate continued year-over-year revenue growth in our core products and from new product launches. We believe gross margins will continue to be positively affected by a more favorable product and geographical mix, as well as increased average selling prices and volumes, partially offset by increased strategic investments in our operational infrastructure. According to data from the Centers for Disease Control and Prevention, current influenza incidence appears to be above the baseline





and has been trending upward. We believe we are appropriately staged for the remaining influenza demand for this 2006/2007 season. Revenues from our iFOB test continue to increase quarter over quarter. We 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 on clinical and economic validation. Additionally, we expect our recently launched RSV product to be a well-received companion test to our QuickVue® Influenza A+B test so that physicians are well prepared to diagnose and appropriately manage patients with influenza and/or RSV. We anticipate continued investment spending in marketing and clinical trials in support of our new product launches and to further validate the clinical efficacy and economic efficiency of our existing products, primarily influenza. We continue to conduct internal and external validations of our tests as compared to several domestic and international competitive tests. We anticipate having results of these studies presented and published in several venues in 2007 and 2008. We also plan to make significant investments in our sales force to further support our leadership position and allow us to take advantage of the large opportunities in POC diagnostics. We expect research and development expense to continue to increase as we expand our capabilities to accelerate innovation and invest in research and development of new technologies.

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**

The following table sets forth for the periods indicated certain consolidated statements of operations data expressed as a percentage of total revenues:

**Consolidated Statements of Operations Data**

	Year Ended December 31,					
	2006		2005		2004	
<b>REVENUES</b>						
Net sales	98.8	%	96.1	%	96.7	%
Research contracts, licenses and royalties	1.2		3.9		3.3	
Total revenues	100.0		100.0		100.0	
<b>COSTS AND EXPENSES</b>						
Cost of sales	42.3		40.2		44.8	
Research and development	12.3		13.9		14.4	
Sales and marketing	16.0		17.5		17.8	
General and administrative	12.0		14.1		18.8	
Patent litigation settlement			18.4			
Amortization of intangibles	4.3		1.6		1.9	
Total costs and expenses	86.9		105.7		97.7	
Operating earnings (loss)	13.1		(5.7)	)	2.3	
<b>OTHER INCOME (EXPENSE)</b>						
Interest income	1.3		0.8		0.5	
Interest expense	(0.7)	)	(0.9)	)	(1.1)	)
Other income	0.5		0.1		0.3	
Total other income (expense)	1.1		(0.0)	)	(0.3)	)
Earnings (loss) from continuing operations before (benefit) provision for income taxes	14.2		(5.8)	)	2.0	
Benefit (provision) for income taxes	5.6		(3.3)	)		
Earnings (loss) from continuing operations	19.8		(9.0)	)	2.0	
Gain (loss) from discontinued operations, net of taxes	0.8		(1.0)	)	(10.0)	)
Net earnings (loss)	20.6	%	(10.0)	)%	(8.0)	)%

*Net Sales*

Net sales increased 18% to \$104.7 million for the year ended December 31, 2006 from \$88.7 million for the year ended December 31, 2005. The increase was largely driven by an increase in sales of our influenza and Group A Strep products of \$9.4 million and \$4.7 million, respectively. The overall increase was partially offset by a decrease of our influenza product revenues in our Japanese market. For the year ended December 31, 2006, we believe revenue to these products has 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 influenza products continue 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. 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. The increase in our Group A Strep product revenues was primarily related to the U.S. and Japanese markets and driven by both increased volume and higher average selling prices. As of December 31, 2006, our U.S. professional market share is an estimated 69% and 47% for our influenza and Group A Strep products, respectively, and we are the market leader in both. The market share data is estimated based on trailing twelve month sales from distribution to end use customers. These two product lines collectively accounted for 64%, 60% and 55% of our net sales for the years ended December 31, 2006, 2005 and 2004.

Net sales increased 17% to \$88.7 million for the year ended December 31, 2005 from \$76.1 million for the year ended December 31, 2004. The increase was largely driven by an increase in sales of our influenza, Group A Strep and pregnancy products of \$8.1 million, \$3.1 million and \$3.0 million, respectively. The overall increases were partially offset by declines in our pregnancy and Group A Strep products in certain international markets. These three product lines collectively accounted for 82% of our net sales for the year ended December 31, 2005.

The increase in sales of our influenza products in 2005 was primarily due to the domestic launch of our new influenza A+B product, timing of the 2004/2005 domestic influenza season and increased sales into the Japanese market. For the year ended December 31, 2004, we experienced decreased sales of our influenza products in Japan due to a weak flu season, which ended abruptly in the early part of the first quarter of 2004 and resulted in significant quantities of our influenza A/B product remaining in our Japanese distribution channel. As a result, our sales were adversely and materially affected during the fourth quarter of 2004 and the first quarter of 2005. According to information provided by our Japanese distributor, significant quantities of our influenza product previously existing in our Japanese distribution channel were significantly reduced as of our third quarter of 2005, which resulted in increased sales in Japan for the year ended December 31, 2005.

The increase in sales of our pregnancy products for the year ended December 31, 2005 was primarily related to increased domestic sales, partially offset by decreased international revenues related to the elimination of lower margin sales in underdeveloped markets as part of the realignment of our global distribution network.

We believe the increase in our Group A Strep product sales for the year ended December 31, 2005 was primarily due to a drop off in orders for Group A Strep test products for the year ended December 31, 2004 resulting from U.S. distributor confusion or concern created by the then ongoing intellectual property litigation with IMA initiated during that period. Additionally, during the quarter ended March 31, 2005, we implemented a price increase in our Group A Strep products.

#### **Research Contracts, License Fees and Royalty Income**

Research contracts, license fees and royalty income decreased to \$1.3 million for the year ended December 31, 2006 from \$3.6 million for the year ended December 31, 2005. 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.

Research contracts, license fees and royalty income increased to \$3.6 million for the year ended December 31, 2005 from \$2.6 million for the year ended December 31, 2004. During 2004, we entered into a joint development agreement with another company and earned \$1.0 million of research contract revenue in connection with achieving certain milestones under a joint development agreement. In connection with this agreement, we received certain upfront non-refundable fees, which had been recorded as deferred revenue and included in other accrued liabilities in our balance sheet as of December 31, 2004. During the second quarter of 2005, the joint development agreement was terminated and the remaining deferred revenue balance of \$0.9 million was recognized as contract revenue. 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 and Gross Profit as a Percentage of Net Sales**

Gross profit from net sales increased to \$59.9 million for the year ended December 31, 2006 from \$51.6 million for the year ended December 31, 2005. Gross profit as a percentage of net sales decreased to 57% for the year ended December 31, 2006 from 58% for the year ended December 31, 2005. The decrease in gross profit as a percentage of sales 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 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 are 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 93%, 91% and 88% of our net sales for the years ended December 31, 2006, 2005 and 2004, respectively. Royalty expense related to this settlement agreement was \$8.2 million and \$4.9 million for the years ended December 31, 2006 and 2005, respectively. If the IMA royalty had been paid for the full year 2005, the royalty expense would have been \$6.9 million. Also for the year ended December 31, 2006, the gross profit as a percentage of sales 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 to this party a 6% royalty on sales of our influenza product. Our influenza products sales accounted for 41%, 38% and 34% of our net sales for the years ended December 31, 2006, 2005 and 2004, respectively.

Gross profit from net sales increased to \$51.6 million for the year ended December 31, 2005 from \$40.8 million for the year ended December 31, 2004. Gross profit as a percentage of net sales increased to 58% for the year ended December 31, 2005 from 54% for the year ended December 31, 2004. The percentage and dollar increase was primarily due to increased sales volume, a more favorable mix related to our influenza products and a decrease in royalties relating to a third party patent which expired in 2004 as well as termination of certain other royalty obligations on our influenza product. The license agreement which expired in 2004 required us to pay royalties ranging from 5% to 5.25% on domestic sales of our influenza, Group A Strep, pregnancy, H. pylori, mononucleosis, Chlamydia and veterinary products. As a result, our royalty expense was favorably impacted by \$3.4 million and \$0.9 million for the years ended December 31, 2005 and 2004, respectively. This increase in gross profit was partially offset by 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 IMA.

### **Research and Development Expense**

Research and development expense increased to \$13.0 million for the year ended December 31, 2006 from \$12.8 million for the year ended December 31, 2005. Research and development expense as a percentage of net sales decreased to 12% of net sales for the year ended December 31, 2006, as compared to 14% of net sales for the year ended December 31, 2005. 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 continue to incur substantial costs related to clinical trials as well as our overall effort under our QVB programs.

Research and development expense increased to \$12.8 million for the year ended December 31, 2005 from \$11.3 million for the year ended December 31, 2004. Research and development expense as a percentage of net sales remained constant at 14% of net sales for the year ended December 31, 2005 and 2004. The absolute dollar increase is primarily attributable to increased personnel related costs, material costs and consulting fees related to our LTF technology platform, and to a lesser extent, clinical trials in support of our QVB programs. These increases were partially offset by a decrease in patent-related expenses during 2005 due to the litigation settlement.

We anticipate that we will continue to devote a significant amount of financial resources to research and development for the foreseeable future.

### **Sales and Marketing Expense**

Sales and marketing expense increased to \$17.0 million for the year ended December 31, 2006 from \$16.1 million for the year ended December 31, 2005. Sales and marketing expense as a percentage of net sales decreased to 16% for the year ended December 31, 2006, from 18% of net sales for the year ended December 31, 2005. 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.

Sales and marketing expense increased to \$16.1 million for the year ended December 31, 2005 from \$14.0 million for the year ended December 31, 2004. Sales and marketing expense as a percentage of net sales remained constant at 18% for the years ended December 31, 2005 and 2004. The absolute dollar increase relates primarily to increased personnel-related costs, marketing programs and events to support our focused efforts on our QVB program and reinforcing relationships with key distributors.

### **General and Administrative Expense**

General and administrative expense decreased to \$12.8 million for the year ended December 31, 2006 from \$13.1 million for the year ended December 31, 2005. General and administrative expense as a percentage of net sales decreased to 12% for the year ended December 31, 2006 from 15% of net sales for the year ended December 31, 2005. The absolute dollar decrease 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 of \$2.1 million.

General and administrative expense decreased to \$13.1 million for the year ended December 31, 2005 from \$14.9 million for the year ended December 31, 2004. General and administrative expense as a percentage of net sales decreased to 15% for the year ended December 31, 2005 from 20% for the year ended December 31, 2004. The absolute dollar decrease was primarily due to a \$3.0 million decrease in legal fees associated with the settlement of our intellectual property litigation, partially offset by \$0.7 million of personnel costs associated with restricted stock compensation expense and management incentives, as well as \$1.0 million related to the CEO changes in 2004.

### *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 Intangibles*

We completed our annual evaluation for impairment of goodwill as of December 31, 2006 and determined that no impairment of goodwill existed. A significant decline in our projected revenue or earnings growth or cash flows, a significant decline in our stock price or the stock price of comparable companies, loss of legal ownership or title to an asset and any significant change in our strategic business objectives and utilization of our assets are among many factors that could result in an impairment charge that could have a material negative impact on our operating results. Our other intangible assets, which are being amortized over a period of two to 12 years, include purchased technology, license agreements, patents, trademarks and a favorable lease.

Amortization expense was \$4.6 million, \$1.5 million and \$1.5 million for each of the years ended December 31, 2006, 2005 and 2004. The increase 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, \$0.7 million and \$0.4 million for the years ended December 31, 2006, 2005 and 2004, respectively, and relates primarily to interest earned on our cash and cash equivalents balance. Interest expense was \$0.8 million, \$0.8 million and \$0.9 million for the years ended December 31, 2006, 2005 and 2004, respectively, 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 and \$0.3 million for the year ended December 31, 2004. During the fourth quarter of 2006, we 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.

The tax expense for the year ended December 31, 2005 was largely due to a partial valuation allowance we established at March 31, 2005 totaling \$3.0 million for a portion of our deferred tax assets. This was primarily as a result of our patent litigation settlement of \$17.0 million recorded during the first quarter of 2005 and the expected effect of future royalty payments under the settlement agreement. Due to the impact of this settlement, we reassessed the realizability of our deferred tax assets, which have been recognized primarily based on projected earnings. As a result of revisions to our estimates of projected earnings, related primarily to the effect of the \$17.0 million settlement payment and future royalty payments, partially offset by a projected reduction in future litigation expenses, we concluded that we could not support the recognition of the same level of deferred tax assets that we had reported on our balance sheet as of December 31, 2004.

#### ***Gain (loss) from discontinued operations, net of taxes***

In the accompanying financial statement, our urinalysis and ultrasonometer businesses are reported as discontinued operations under SFAS No. 144 *Accounting for the Impairment or Disposal of Long-Lived Assets*. We discontinued all operations of our ultrasonometer business during the fourth quarter of 2004. During the second quarter of 2005, we sold certain assets of our urinalysis business for \$0.5 million. Accordingly, the operations of both businesses have been classified as discontinued operations in the statements of operations for all periods presented. During the fourth quarter of 2006, we finalized our open tax audits in Germany and recognized a non-cash gain on discontinued operations of approximately \$0.8 million associated with certain remaining balance sheet credits related to the urinalysis operation sold during 2005. The loss from discontinued operations, net of taxes, was \$0.9 million and \$7.9 million for the years ended December 31, 2005 and 2004, respectively.

#### **Liquidity and Capital Resources**

As of December 31, 2006, our principal source of liquidity consisted of \$36.6 million in cash and cash equivalents. Our working capital as of December 31, 2006 was \$53.1 million.

Our earnings from continuing operations provided net cash of \$20.7 million for the year ended December 31, 2006. We had net earnings of \$21.7 million and \$9.1 million of depreciation and amortization of intangible assets and \$3.4 million of non-cash stock compensation expense. We experienced a decrease in accounts receivable, inventories and accounts payable of \$2.3 million, \$1.1 million and \$1.3 million, respectively, for the year ended December 31, 2006, due primarily to seasonal demand fluctuations of our influenza and Group A Strep products. Other changes in liabilities included a decrease in other current liabilities of \$1.1 million as of December 31, 2006 related primarily to fulfillment of contractual obligations associated with the acquisition of our iFOB test.

Our investing activities used \$10.7 million of cash during the year ended December 31, 2006, primarily driven by the acquisition of manufacturing equipment, building improvements and the acquisition of a license agreement related to certain intellectual property.

Our financing activities used \$8.4 million of cash during the year ended December 31, 2006 and were related primarily to the repurchase of \$11.6 million of our common stock and \$0.6 million for payments on obligations under our capital leases related to our building in San Diego. These items were partially offset by proceeds of \$3.7 million from the issuance of common stock under our equity incentive plans. In March 2007, our Board of Directors authorized us to repurchase up to an additional \$25 million in shares of our common stock under our previously announced share repurchase program. See Note 10. Subsequent Events in the Notes to Consolidated Financial Statements included in this Annual Report.

We are planning approximately \$6.0 million in capital expenditures for 2007. The primary purpose for our capital expenditures is to acquire manufacturing equipment, implement facility expansion and 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 expenditures as of the date of filing this Annual Report.

We currently have a \$30.0 million credit facility (the Senior Secured Credit Facility), which has a three and a half year term, maturing on June 30, 2008. The Senior Secured Credit Facility is secured by substantially all of our assets and bears interest at a rate ranging from 0% to 1% plus the lender's prime rate or, at our option, a rate ranging from 1.0% to 2.0% plus the London InterBank Offering Rate. The agreement governing our Senior Secured 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 Secured Credit Facility require us to comply with certain financial covenants, including: a minimum net worth, a maximum ratio of debt drawn under the Senior Secured Credit Facility to earnings before interest, taxes, depreciation and amortization (EBITDA), a fixed charge coverage ratio, and minimum EBITDA. As of December 31, 2006, we had no borrowings outstanding under the Senior Secured Credit Facility and we were in material compliance with all covenants.

#### **Off-Balance Sheet Arrangements**

At December 31, 2006 and 2005, 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. We also have obligations and commitments related to an asset purchase and licensing agreement. 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)	\$ 11,817	\$ 1,377	\$ 2,836	\$ 2,951	\$ 4,653
Operating lease obligations(2)	4,501	1,337	3,119	45	
Asset purchase and license agreement(3)	2,166	2,166			
Total	\$ 18,484	\$ 4,880	\$ 5,955	\$ 2,996	\$ 4,653

(1) Reflects obligations on facilities and equipment under capital leases, including current maturities, in place as of December 31, 2006. 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, 2006. Future minimum lease payments are included in the table above.

(3) Reflects obligations resulting from firm purchase commitments for inventory components of \$2.2 million.

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 \$9.6 million, \$7.1 million and \$5.6 million for the years ended December 31, 2006, 2005 and 2004, 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 December 31, 2005, 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 earnings (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 is based on our historical experience.

Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option award. The total number of stock options expected to vest is adjusted by estimated forfeiture rates. The estimated fair value of each stock option was determined on the date of grant using the Black-Scholes option valuation model. Compensation expense for restricted stock awards ( stock awards ) is measured at the grant date and recognized ratably over the vesting period. The fair value of stock awards is determined based on the closing market price of our common stock on the grant date. The total amount of unrecognized compensation cost related to nonvested stock awards as of December 31, 2006 was approximately \$3.7 million, which is expected to be recognized over a weighted-average period of approximately 2.2 years. 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 March 2006 were performance based and vesting is tied to achievement of our 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. A significant portion of our stock grants contains performance-based 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. 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 grant. 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.

#### *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 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 classified under revenues as research contracts, license fees and royalty income 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 twelve 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.

#### *Intangibles*

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, 2006 and determined that no impairment of goodwill existed.

#### *Income Taxes*

A valuation allowance of \$18.2 million had been established against a portion of the our deferred tax assets at December 31, 2005. As of December 31, 2006, we believed it is more likely than not that we will be able to realize our deferred tax asset through expected future taxable profits, and released a valuation allowance of approximately \$18.2 million of which \$11.6 million was recognized as an income tax benefit and \$6.6 million reduced the existing value of goodwill. Although realization is not assured, we have concluded that it is more likely than not that the deferred tax assets at December 31, 2006 for which a valuation allowance was determined to be unnecessary will be realized in the ordinary course of operations based on the available positive and negative evidence, primarily our projected earnings. The amount of the net deferred tax assets considered realizable, however, could be reduced in the near term if actual future earnings or income tax rates are lower than estimated, or if there are differences in the timing or amount of future reversals of existing taxable or deductible temporary differences.

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, 2006 and 2005, deferred tax assets do not include \$6.0 million and \$3.9 million, respectively of these excess tax benefits from employee stock option exercises that are a component of our net operating loss carryforwards. Deferred taxes and the valuation allowance as of December 31, 2005 have been restated in order to conform to the 2006 presentation. Additional paid in capital will be increased up to \$6.0 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.

## Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109 ( FIN No. 48 ), which clarifies the accounting and disclosure for uncertainty in tax positions, as defined. FIN 48 seeks to reduce the diversity in practice associated with certain aspects of the recognition and measurement related to accounting for income taxes. This interpretation is effective for fiscal years beginning after December 15, 2006. The cumulative effect of applying the provisions of FIN No. 48 will be reported as an adjustment to the beginning balance of retained earnings for that fiscal year. We are currently evaluating the impact that the adoption of FIN No. 48 will have, if any, on our consolidated financial statements and notes thereto.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, ( SFAS No. 157 ). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the U.S., and expands disclosures about fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007, with earlier application encouraged. Any amounts recognized upon adoption as a cumulative effect adjustment will be recorded to the beginning balance of retained earnings in the year of adoption. We have not yet determined the impact of SFAS No. 157 on our financial condition and results of operations.

## 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, 2006. Based on our market risk sensitive instruments outstanding at December 31, 2006 and 2005, 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, 2006, our cash and cash equivalents were placed in money market and/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 Principal Financial and Accounting Officer ( PFAO ), 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 PFAO concluded that our disclosure controls and procedures were effective as of December 31, 2006 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 2006 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 PFAO, 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, 2006.

Management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006 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 management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Quidel Corporation maintained effective internal control over financial reporting as of December 31, 2006, 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. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of 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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, 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, management's assessment that Quidel Corporation maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Quidel Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, 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, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2006 and our report dated March 12, 2007 expressed an unqualified opinion thereon.

Ernst & Young LLP

San Diego, California  
March 12, 2007

**Item 9B. Other Information**

**2007 Annual Meeting of Stockholders**

The Company's 2007 Annual Meeting of Stockholders will be held on Wednesday, May 7, 2007, beginning at 8:30 a.m. (local time) at Hyatt Regency in La Jolla, California.

**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 2007 Proxy Statement, which will be filed with the SEC no later than April 30, 2007. 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 2007 Proxy Statement, which will be filed with the SEC no later than April 30, 2007.

**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 2007 Proxy Statement to be filed with the SEC no later than April 30, 2007.

**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 2007 Proxy Statement, which will be filed with the SEC no later than April 30, 2007.

**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 2007 Proxy Statement, which will be filed with the SEC no later than April 30, 2007.

**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 2007 Proxy Statement, which will be filed with the SEC no later than April 30, 2007.

**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**

<u>Report of Independent Registered Public Accounting Firm on Financial Statements</u>	F-1
<u>Consolidated Balance Sheets at December 31, 2006 and 2005</u>	F-2
<u>Consolidated Statements of Operations for the years ended December 31, 2006, 2005 and 2004</u>	F-3
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2006, 2005 and 2004</u>	F-4
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-6

(2) Financial Statement Schedules

The following Financial Statement Schedule of Quidel Corporation for the years ended December 31, 2006, 2005 and 2004 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.

Date: March 14, 2007

QUIDEL CORPORATION  
 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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ CAREN L. MASON Caren L. Mason	President, Chief Executive Officer (Principal Executive Officer), and Director	March 14, 2007
/s/ PAUL E. LANDERS Paul E. Landers	Principal Financial and Accounting Officer	March 14, 2007
/s/ MARK A. PULIDO Mark A. Pulido	Chairman of the Board	March 12, 2007
/s/ THOMAS D. BROWN Thomas D. Brown	Director	March 14, 2007
/s/ DOUGLAS S. HARRINGTON Douglas S. Harrington	Director	March 14, 2007
/s/ RODNEY F. DAMMEYER Rodney F. Dammeyer	Director	March 14, 2007
/s/ MARY LAKE POLAN Mary Lake Polan	Director	March 14, 2007
/s/ JACK W. SCHULER Jack W. Schuler	Director	March 14, 2007

**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, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2006. 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 as of December 31, 2006 and 2005, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2006 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 changed its method of accounting for Share-Based Payments in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004) on January 1, 2006.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Quidel Corporation's internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 12, 2007 expressed an unqualified opinion thereon.

ERNST & YOUNG LLP

San Diego, California  
March 12, 2007

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## QUIDEL CORPORATION

## CONSOLIDATED BALANCE SHEETS

(in thousands, except par value)

	December 31, 2006	2005
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 36,625	\$ 34,930
Accounts receivable, net	18,139	15,819
Inventories	9,625	8,500
Deferred tax asset - current	1,590	
Prepaid expenses and other current assets	1,690	1,354
Total current assets	67,669	60,603
Property, plant and equipment, net	20,058	19,557
Intangible assets, net	18,797	23,964
Deferred tax asset - non-current	20,065	8,864
Other non-current assets	459	860
Total assets	\$127,048	\$ 113,848
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,832	\$ 5,134
Accrued payroll and related expenses	1,976	1,847
Accrued royalties	3,559	3,367
Current portion of obligations under capital leases	675	648
Other current liabilities	4,564	5,623
Total current liabilities	14,606	16,619
Capital leases, net of current portion	7,764	8,439
Deferred rent	1,402	1,547
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.001 par value per share; 5,000 shares authorized, none issued or outstanding at December 31, 2006 and 2005		
Common stock, \$.001 par value per share; 50,000 shares authorized, 33,530 and 33,778 shares issued and outstanding at December 31, 2006 and 2005, respectively	33	34
Deferred stock compensation		(1,947 )
Additional paid-in capital	155,357	161,662
Accumulated other comprehensive earnings		1,326
Accumulated deficit	(52,114 )	(73,832 )
Total stockholders' equity	103,276	87,243
Total liabilities and stockholders' equity	\$ 127,048	\$ 113,848

See accompanying notes.

## QUIDEL CORPORATION

## CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,		
	2006	2005	2004
	(in thousands, except per share data)		
<b>REVENUES</b>			
Net sales	\$ 104,732	\$ 88,731	\$ 76,072
Research contracts, license fees and royalty income	1,283	3,568	2,619
Total revenues	106,015	92,299	78,691
<b>COSTS AND EXPENSES</b>			
Cost of sales	44,818	37,101	35,234
Research and development	13,047	12,829	11,340
Sales and marketing	16,966	16,121	13,990
General and administrative	12,770	13,062	14,852
Patent litigation settlement		17,000	
Amortization of intangibles	4,580	1,476	1,459
Total costs and expenses	92,181	97,589	76,875
Operating earnings (loss)	13,834	(5,290 )	1,816
<b>OTHER INCOME (EXPENSE)</b>			
Interest income	1,408	722	398
Interest expense	(757 )	(808 )	(886 )
Other income	545	49	256
Total other income (expense)	1,196	(37 )	(232 )
Earnings (loss) from continuing operations before (benefit) provision for income taxes	15,030	(5,327 )	1,584
(Benefit) provision for income taxes	(5,891 )	3,000	
Earnings (loss) from continuing operations	20,921	(8,327 )	1,584
Gain (loss) from discontinued operations, net of taxes	797	(932 )	(7,871 )
Net earnings (loss)	\$ 21,718	\$ (9,259 )	\$ (6,287 )
Basic earnings (loss) per share:			
Continuing operations	\$ 0.63	\$ (0.26 )	\$ 0.05
Discontinued operations	0.02	(0.03 )	(0.25 )
Net earnings (loss)	0.66	(0.28 )	(0.20 )
Diluted earnings (loss) per share:			
Continuing operations	\$ 0.61	\$ (0.26 )	\$ 0.05
Discontinued operations	0.02	(0.03 )	(0.25 )
Net earnings (loss)	0.63	(0.28 )	(0.20 )
Shares used in basic per share calculations	32,985	32,525	31,487
Shares used in diluted per share calculations	34,367	32,525	32,386

See accompanying notes.

## QUIDEL CORPORATION

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock		Additional paid-in capital	Deferred stock compensation	Accumulated other comprehensive earnings (loss)	Accumulated deficit	Total stockholders equity	Total comprehensive earnings (loss)
	Shares (in thousands)	Amount						
Balance at December 31, 2003	30,406	\$ 31	\$ 146,836	\$	\$ 1,199	\$ (58,286)	\$ 89,780	\$ 20,544
Issuance of common stock for cash under stock options and stock purchase plans	1,442	1	6,432				6,433	
Income tax benefit due to exercise/ disposition of employee stock options			51				51	
Translation adjustment					208		208	\$ 208
Net loss						(6,287 )	(6,287 )	(6,287 )
Balance at December 31, 2004	31,848	32	153,319		1,407	(64,573 )	90,185	\$ (6,079 )
Issuance of common stock for cash under stock options and stock purchase plans	1,421	1	6,068				6,069	
Deferred stock compensation relating to restricted stock	610	1	2,757	(2,757 )			1	
Cancellation of restricted stock compensation	(30 )		(130 )	130				
Amortization of deferred stock compensation				680			680	
Translation adjustment					(81 )		(81 )	\$ (81 )
Purchase of common stock	(71 )		(352 )				(352 )	
Net loss						(9,259 )	(9,259 )	(9,259 )
Balance at December 31, 2005	33,778	34	161,662	(1,947 )	1,326	(73,832 )	87,243	\$ (9,340 )
Issuance of common stock under equity compensation plans	998	1	3,697				3,698	
Income tax benefit due to exercise/disposition of employee stock options			111				111	
Cancellation of common stock under equity compensation plans	(24)							
Reclassification due to adoption of SFAS 123R			(1,947 )	1,947				
Stock-based compensation expense			3,398				3,398	
Translation adjustment					(1,326 )		(1,326 )	\$ 1,326
Purchase of common stock	(1,222 )	(2 )	(11,564 )				(11,566 )	
Net earnings						21,718	21,718	21,718
Balance at December 31, 2006	33,530	\$ 33	\$ 155,357	\$	\$	\$ (52,114)	\$ 103,276	\$ 23,044

See accompanying notes.

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**QUIDEL CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year ended December 31,		
	2006	2005	2004
	(in thousands)		
<b>OPERATING ACTIVITIES</b>			
Net earnings (loss)	\$ 21,718	\$ (9,259 )	\$ (6,287 )
Adjustments to reconcile net earnings (loss) to net cash provided by operating activities:			
Depreciation and amortization	9,109	5,466	5,544
(Gain) loss on discontinued operations	(797 )	932	7,871
Foreign currency translation	(558 )		
Loss on disposal of assets	16	66	62
Stock-based compensation expense	3,398	680	
Change in deferred tax asset	(6,078 )	2,887	441
Excess tax benefit from share based compensation	(111 )		
Changes in assets and liabilities:			
Accounts receivable	(2,320 )	(545 )	8,869
Inventories	(1,125 )	(860 )	(295 )
Prepaid expenses and other current assets	(336 )	152	99
Accounts payable	(1,302 )	842	(941 )
Accrued payroll and related expenses	129	492	229
Accrued royalties	192	1,162	(1,245 )
Deferred rent	(145 )	(145 )	111
Deferred revenue		(1,629 )	43
Other current liabilities	(1,059 )	1,160	(2,549 )
Net cash provided by continuing operations	20,731	1,401	11,952
Net cash used by discontinued operations		(179 )	(2,028 )
Net cash provided by operating activities	20,731	1,222	9,924
<b>INVESTING ACTIVITIES</b>			
Acquisition of plant and equipment	(4,469 )	(3,157 )	(4,623 )
Net increase in intangible assets	(6,500 )	(4,300 )	(815 )
Other assets	308	(211 )	128
Net cash used for investing activities	(10,661 )	(7,668 )	(5,310 )
<b>FINANCING ACTIVITIES</b>			
Proceeds from issuance of common stock, net	3,697	5,717	6,484
Excess tax benefit from share based compensation	111		
Payments on debt and obligations under capital leases	(648 )	(590 )	(519 )
Purchase of common stock	(11,564 )		
Net cash provided by (used for) financing activities	(8,404 )	5,127	5,965
Effect of exchange rate changes on cash	29	(73 )	116
Net increase (decrease) in cash and cash equivalents	1,695	(1,392 )	10,695
Cash and cash equivalents at beginning of year	34,930	36,322	25,627
Cash and cash equivalents at end of year	\$ 36,625	\$ 34,930	\$ 36,322
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION</b>			
Cash paid for interest	\$ 757	\$ 808	\$ 856
Cash paid for income taxes	\$	\$	\$ 310
<b>NON-CASH INVESTING ACTIVITIES</b>			
Purchase of license agreements by incurring current liabilities	\$	\$ 2,800	\$

See accompanying notes.

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

Quidel Corporation (the Company) commenced operations in 1979. The Company operates in one business segment, which develops, manufactures and markets point-of-care (POC) rapid diagnostics for detection and management of a variety of medical conditions and illnesses. The majority of the Company's products are specifically developed for the physician office lab and acute care market and are substantially focused on infectious diseases and reproductive health. The Company's products are sold to professionals for use in physician offices, hospitals, clinical laboratories and wellness screening centers through a network of national and regional distributors, supported by a national sales force.

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

*Reclassification* Certain amounts from the prior year have been reclassified to conform to the December 31, 2006 financial statement presentation.

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

*Accounts Receivable* The Company sells its products primarily to distributors in the U.S., Europe and Japan. The Company periodically assesses the financial strength of these customers and establishes reserves for anticipated losses when necessary, which historically have not been material. The Company's reserves primarily consist of amounts related to cash discounts and contract rebates, and to a lesser extent returned good allowances and bad debts. The balance of accounts receivable is net of reserves of \$0.8 million and \$1.1 million at December 31, 2006 and 2005, respectively.

*Inventories* Inventories are stated at the lower of cost (first-in, first-out method) or market. The Company reviews the components of its inventory on a quarterly basis for excess, obsolete and impaired inventory and makes appropriate dispositions as obsolete stock is identified. Inventories consisted of the following, net of reserves of \$0.2 million for both years ended December 31, 2006 and 2005, (in thousands):

	December 31,	
	2006	2005
Raw materials	\$ 4,296	\$ 3,414
Work-in-process	2,692	2,682
Finished goods	2,637	2,404
	\$ 9,625	\$ 8,500

*Property, Plant and Equipment* Property, plant and equipment is recorded at cost and depreciated over the estimated useful lives of the assets (three to 15 years) using the straight-line method. Amortization of leasehold improvements is computed on the straight-line method over the shorter of the lease term or the estimated useful lives of the assets. The total expense for depreciation of fixed assets and amortization of leasehold improvements was \$4.0 million, \$3.7 million and \$3.8 million for the years ended December 31, 2006, 2005 and 2004, respectively. The portion of this expense related to capital leases is \$0.6 million, \$0.6 million, and \$0.5 million for the years ended December 31, 2006, 2005 and 2004. Maintenance and minor repairs are charged to operations as incurred. When assets are sold, or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and any gain or loss is included in Other Income (Expenses) in the Consolidated Statement of Operations.



**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Equipment, furniture and fixtures	\$ 35,762	\$ 33,836
Building and improvements	18,744	17,717
Land	1,080	1,080
	55,586	52,633
Less: Accumulated depreciation and amortization	(35,528 )	(33,076 )
	\$ 20,058	\$ 19,557

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

Description	Weighted Average Life	December 31, 2006			December 31, 2005		
		Gross Assets	Accumulated Amortization	Net	Gross Assets	Accumulated Amortization	Net
Goodwill	NA	\$ 9,918	\$ (3,448 )	\$ 6,470	\$ 16,520	\$ (3,448 )	\$ 13,072
Purchase Technology	7.0	6,100	(5,231 )	869	6,100	(4,359 )	1,741
License Agreements	4.0	16,300	(6,383 )	9,917	10,400	(3,234 )	7,166
Patent and trademark costs	5.3	3,623	(2,641 )	982	3,623	(2,386 )	1,237
Favorable lease	9.0	1,700	(1,141 )	559	1,700	(952 )	748
		\$ 37,641	\$ (18,844 )	\$ 18,797	\$ 38,343	\$ (14,379 )	\$ 23,964

Amortization expense was \$4.6 million, \$1.5 million and \$1.5 million for the years ended December 31, 2006, 2005 and 2004, respectively. During the fourth quarter of 2006, goodwill was reduced by \$6.6 million due to the removal of a valuation allowance on deferred tax assets related to net operating losses of acquired companies.

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

Years Ended December 31,	Amortization Expense
2007	\$ 5,375
2008	4,238
2009	1,333
2010	1,152
2011	139
Thereafter	
Total	\$ 12,237

On January 1, 2002, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 142 *Goodwill and Other Intangible Assets*, ( SFAS No. 142 ) which requires that goodwill and other intangible assets that have indefinite lives not be amortized but instead be tested at least annually for

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

impairment, or more frequently when events or changes in circumstances indicate that the asset might be impaired by comparing the carrying value 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 goodwill impairment, if any. The first step is to compare the fair value of a reporting unit with its 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 also requires periodic evaluations for impairment of goodwill. The Company completed its annual evaluation for impairment of goodwill as of December 31, 2006, and determined that no impairment of goodwill existed. A significant decline in the Company's projected revenue or earnings growth or cash flows, a significant decline in the Company's stock price or the stock price of comparable companies, loss of legal ownership or title to an asset, and any significant change in the Company's strategic business objectives and utilization of assets are among many factors that could result in an impairment charge that could have a material negative impact on the Company's operating results.

*Impairment of Long-Lived Assets* In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, the Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the total book value of an asset may not be recoverable. An impairment loss is recognized when estimated undiscounted future cash flows expected to result from the use of the asset and the eventual disposition are less than its carrying amount. An impairment loss is equal to the excess of the book value of an asset over its determined fair value. See *Discontinued Operations* in Note 9 below.

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

	December 31,	
	2006	2005
Accrued compensation	\$ 2,892	\$ 1,675
Product acquisition liabilities		2,500
Volume discounts payable	596	285
State and foreign taxes payable	688	354
Accrued professional fees	213	224
Other	175	585
	\$ 4,564	\$ 5,623

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

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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) the Company's 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 the Company's performance obligations under the agreement. Income earned from licensing activities is classified under revenues as research contracts, license fees and royalty income in the accompanying Consolidated Statements of Operations.

*Research and Development Costs* All research and development costs are charged to operations as incurred.

*Product Shipment Costs* Product shipment costs are included in sales and marketing expense in the accompanying consolidated statements of operations. Shipping and handling costs were \$1.5 million, \$1.1 million and \$0.9 million for the years ended December 31, 2006, 2005 and 2004, respectively.

*Advertising Costs* Advertising costs are expensed as incurred. Advertising costs were \$0.5 million, \$0.9 million and \$1.2 million for the years ended December 31, 2006, 2005 and 2004, respectively.

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

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

*Foreign Currency Translation* The financial statements of the Company's subsidiaries outside the U.S. are measured using the local currency as the functional currency. Assets and liabilities of these subsidiaries are translated at the rates of exchange at the balance sheet date and revenue and expense accounts are translated using average exchange rates during the periods. The resulting translation adjustments are presented as a separate component of stockholders' equity. Exchange gains and losses arising from transactions denominated in foreign currencies are recorded in operations and have historically not been significant.

*Fair Value of Financial Instruments* The carrying amounts of the Company's financial instruments, including cash, receivables, accounts payable, accrued liabilities and the line of credit, if any, approximate their fair values due to their short-term nature. Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of trade accounts receivable. The Company establishes reserves for estimated uncollectible accounts and believes its reserves are adequate.

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*Stock Compensation* Prior to January 1, 2006, the Company accounted for share-based employee and director compensation, including stock options, using the method prescribed in Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees and related Interpretations (APB Opinion No. 25). Under APB Opinion No. 25, for stock options granted with an exercise price at or above market price, no compensation cost was recognized, and a disclosure was made regarding the pro forma effect on net earnings assuming compensation cost had been recognized in accordance with SFAS No. 123, Accounting for Stock-Based Compensation. On December 16, 2004, the Financial Accounting Standards Board issued SFAS No. 123 (Revised 2004) Share Based Payment ( SFAS No. 123(R) ), which requires companies to measure and recognize compensation expense for all share-based payments at fair value. SFAS No. 123(R) eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, and generally requires that such transactions be accounted for using prescribed fair-value-based methods. SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods: (a) a modified prospective method in which compensation costs are recognized beginning with the effective date based on the requirements of SFAS No. 123(R) for all share-based payments granted or modified after the effective date, and based on the requirements of SFAS No. 123 for all awards granted to employees and directors prior to the effective date of SFAS No. 123(R) that remain unvested on the effective date, or (b) a modified retrospective method which includes the requirements of the modified prospective method described above, but also permits companies to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures either for all periods presented, or prior interim periods of the year of adoption. Effective January 1, 2006, the Company adopted SFAS No. 123(R) using the modified prospective method. Other than restricted stock, no share-based employee or director compensation cost has been reflected in net income prior to the adoption of SFAS No. 123(R). Results for prior periods have not been restated.

*Computation of Earnings (Loss) Per Share* Basic earnings per share were computed by dividing net earnings by the weighted-average number of common shares outstanding, including vested restricted stock awards, during the period. Diluted earnings per share reflects the potential dilution that could occur if the earnings were divided by the weighted-average number of common shares and potentially dilutive common shares from outstanding stock options as well as unvested restricted stock awards. Potential dilutive common shares were calculated using the treasury stock method and represent incremental shares issuable upon exercise of the Company's outstanding stock options and unvested restricted stock awards. The Company has awarded restricted stock with both service-based as well as performance-based vesting provisions. Stock awards based on performance only are not included in the calculation of earnings per share until the performance criteria are met. For periods in which we incur losses, potentially dilutive shares are not considered in the calculation of net loss per share as their impact would be anti-dilutive. For periods in which we have earnings, out-of-the-money stock options (i.e., the average stock price during the period is below the exercise price of the stock option) are not included in diluted earnings per common share as their effect is anti-dilutive.

During the year ended December 31, 2006, we had earnings from continuing operations. Accordingly, 0.4 million shares of outstanding stock options were not included in the computation of diluted earnings per common share because the option exercise price was greater than the average market price of the common stock, and therefore, the effect on dilutive earnings per common share would be anti-dilutive. For the year ended December 31, 2005, we incurred losses from continuing operations. Potentially dilutive

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

shares of 1.4 million are not considered in the calculation of net loss per share, as their impact would be anti-dilutive.

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

	Year ended December 31,		
	2006	2005	2004
Shares used in basic earnings (loss) per share (weighted-average common shares outstanding)	32,985	32,525	31,487
Effect of dilutive stock options and restricted stock awards	1,382		899
Shares used in diluted earnings (loss) per share calculation	34,367	32,525	32,386

*Comprehensive Earnings (Loss)* *Comprehensive* earnings (loss) includes unrealized gains and losses excluded from the Company's Consolidated Statements of Operations. The unrealized losses include foreign currency translation adjustments. The Company has presented the required information in the consolidated statements of stockholders equity.

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

*New Accounting Standards* In July 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109* ( FIN No. 48 ), which clarifies the accounting and disclosure for uncertainty in tax positions, as defined. FIN No. 48 seeks to reduce the diversity in practice associated with certain aspects of the recognition and measurement related to accounting for income taxes. This interpretation is effective for fiscal years beginning after December 15, 2006. The cumulative effect of applying the provisions of FIN No. 48 will be reported as an adjustment to the beginning balance of retained earnings for that fiscal year. The Company is currently evaluating the impact that the adoption of FIN No. 48 will have, if any, on its consolidated financial statements and notes thereto.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the U.S., and expands disclosures about fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007, with earlier application encouraged. Any amounts recognized upon adoption as a cumulative effect adjustment will be recorded to the beginning balance of retained earnings in the year of adoption. The Company has not yet determined the impact of SFAS No. 157 on its financial condition and results of operations.

*Accounting Periods* The Company's first, second and third fiscal quarters end on the Sunday closest to March 31, June 30 and September 30, respectively. The Company's fiscal year end is December 31. For ease of reference, the calendar quarter end date is used herein.

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Line of Credit**

As of December 31, 2006, the Company had a \$30.0 million credit facility (the Senior Secured Credit Facility), which has a three and a half year term, maturing on June 30, 2008. The Senior Secured Credit Facility is secured by substantially all of the Company's assets and bears interest at a rate ranging from 0% to 1% plus the lender's prime rate or, at the Company's option, a rate ranging from 1.0% to 2.0% plus the London InterBank Offering Rate. The agreement governing the Senior Secured Credit Facility contains certain customary covenants restricting the Company's 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 Secured Credit Facility require the Company to comply with certain financial covenants, including a minimum net worth, a maximum ratio of debt drawn under the Senior Secured Credit Facility to earnings before interest, taxes, depreciation and amortization (EBITDA), a fixed charge coverage ratio, and minimum EBITDA. As of December 31, 2006, there were no borrowings outstanding under the Senior Secured Credit Facility and the Company was in material compliance with all covenants.

**Note 3. Income Taxes**

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

	<b>December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
United States	\$ 14,524	\$ (5,272 )	\$ 279
Foreign	506	(55 )	1,305
	\$ 15,030	\$ (5,327 )	\$ 1,584

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

	<b>December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Current:</b>			
Federal	\$ 181	\$	\$
State	113	113	(441 )
Total current provision	294	113	(441 )
<b>Deferred:</b>			
Federal	(5,072 )	2,368	
State	(1,113 )	519	441
Total deferred provision	(6,185 )	2,887	441
(Benefit) provision for income taxes	\$ (5,891 )	\$ 3,000	\$

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 3. Income Taxes (Continued)**

Significant components of the Company's deferred tax assets as of December 31, 2006 and 2005 are shown below (in thousands).

	December 31, 2006	2005
Deferred tax assets:		
Net operating loss carryforwards	\$ 9,273	\$ 13,857
Capitalized research and development costs	4,946	6,688
Tax credit carryforwards	1,828	2,466
Depreciation	296	17
Other, net	5,670	5,038
Total deferred tax assets	22,013	28,066
Valuation allowance for deferred tax assets		(18,217 )
Deferred tax assets, net of valuation allowance	22,013	9,849
Deferred tax liabilities:		
Acquired intangibles	(358 )	(985 )
Net deferred tax assets	\$ 21,655	\$ 8,864

A valuation allowance of \$18.2 million had been established against a portion of the Company's deferred tax assets at December 31, 2005. As of December 31, 2006, the Company believed it is more likely than not that it will be able to realize its deferred tax asset through expected future taxable profits, and released a valuation allowance of approximately \$18.2 million of which \$11.6 million was recognized as an income tax benefit and \$6.6 million reduced the existing value of goodwill. Although realization is not assured, the Company has concluded that it is more likely than not that the deferred tax assets at December 31, 2006 for which a valuation allowance was determined to be unnecessary will be realized in the ordinary course of operations based on the available positive and negative evidence, primarily the Company's projected earnings. The amount of the net deferred tax assets considered realizable, however, could be reduced in the near term if actual future earnings or income tax rates are lower than estimated, or if there are differences in the timing or amount of future reversals of existing taxable or deductible temporary differences.

As a result of the adoption of SFAS No. 123(R) the Company 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 (NOL) resulting from excess tax benefits. As of December 31, 2006 and 2005, deferred tax assets do not include \$6.0 million and \$3.9 million, respectively of these excess tax benefits from employee stock option exercises that are a component of the Company's net operating loss carryforwards. Deferred taxes and the valuation allowance as of December 31, 2005 have been restated in order to conform to the 2006 presentation. Additional paid in capital will be increased up to \$6.0 million if such excess tax benefits are realized.

The Company will continue to assess the assumptions used to determine the valuation allowance. Should the Company determine that it would not be able to realize all or part of its other components of the deferred tax asset in the future, an adjustment to the deferred tax asset would be charged to earnings in the period such determination were made.

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 3. Income Taxes (Continued)**

As of December 31, 2006, the Company had federal NOL carryforwards of approximately \$43.5 million, including an acquired NOL of approximately \$20.9 million. Approximately \$3.5 million of the carryforwards are scheduled to expire during 2007, unless previously utilized. The balance of the federal NOL carryforwards will expire at various dates through December 31, 2025, unless previously utilized. The Company has state NOL carryforwards of \$10.9 million. None of the state NOL carryforwards are scheduled to expire during 2007. The balance of the NOL carryforwards will expire at various dates through 2015. The Company has gross federal and state research credits of \$0.8 million and \$2.4 million, respectively. The federal credits begin to expire in 2012 and the state credits do not expire. The Company also has an alternative minimum tax credit of \$1.0 million that does not expire.

**Pursuant to Internal Revenue Code Sections 382 and 383, the Company's use of its net operating loss and credit carryforwards may be limited as a result of cumulative changes in ownership of more than 50% over a three-year period.**

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

	<b>Year ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Tax expense (benefit) at statutory tax rate	\$ 5,110	\$ (1,811 )	\$ 539
Permanent differences	462		
Federal and state research credits - current year	(458 )	(397 )	(343 )
Federal and state research credits - prior year true-up	1,235	(294 )	(922 )
Foreign taxes and foreign (income) losses not benefited (taxed)	(194 )	19	
State taxes (benefit), net of federal tax (benefit)	735	(234 )	74
Federal and state NOL change related to section 382	(1,103 )	1,372	
Change in valuation allowance	(11,612 )	4,289	913
Other	(66 )	56	(261 )
	\$ (5,891 )	\$ 3,000	\$

**Note 4. Stockholders' Equity**

*Preferred Stock.* The Company's certificate of incorporation, as amended, authorizes the issuance of up to 5 million preferred shares. The Board of Directors is authorized to fix the number of shares of any series of preferred stock and to determine the designation of such shares. However, the amended certificate of incorporation specifies the initial series and the rights of that series. No shares of preferred stock were outstanding as of December 31, 2006 and 2005.

*Stockholder Rights Plan.* The Board of Directors of the Company adopted a Stockholder Rights Plan, effective December 31, 1996 and as amended and restated, effective May 24, 2002 and then again on December 29, 2006 (the Rights Plan), which provides for a dividend of one right (a Right) to purchase fractions of shares of the Company's Series C Junior Participating Preferred Stock for each share of the Company's common stock. Under certain conditions involving an acquisition by any person or group of



**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 4. Stockholders Equity (Continued)**

15% or more of the common stock, the Rights permit the holders (other than the 15% holder) to purchase the Company's common stock at a 50% discount upon payment of an exercise price of \$24 per Right. In addition, in the event of certain business combinations, the Rights permit the purchase of the common stock of an acquiror at a 50% discount. Under certain conditions, the Rights may be redeemed by the Board of Directors in whole, but not in part, at a price of \$.005 per Right. The Rights have no voting privileges and are attached to and automatically trade with the Company's common stock. The Rights shall expire on December 31, 2011, unless earlier triggered, redeemed or exchanged.

*Restricted Stock.* For the year ended December 31, 2006, the Company granted approximately 0.3 million shares of restricted common stock to officers and management. The shares of restricted stock awarded to officers during 2006 are all performance based and remain subject to forfeiture until the restrictions covering such restricted shares lapse. The lapse of restrictions covering two-thirds of the total number of shares of these restricted shares (the Annual Shares) is tied to the achievement of annual performance targets for the Company over a three year period. Assuming the officer remains employed by the Company on the relevant date, restrictions lapse on one-third of these Annual Shares each year on the anniversary of the grant date in 2007, 2008 and 2009 upon the Company's achievement of the annual goals set by the Company's Board of Directors with respect to revenue, EBITDA and a key strategic imperative for the Company in each of the fiscal years ending in 2006, 2007 and 2008, respectively. The lapse of restrictions on the remaining one-third of the total number of shares of these restricted shares is tied to the Company's achievement of a three-year EBITDA goal, as determined by the board of directors, with restrictions lapsing on the third anniversary of the grant date if such EBITDA goal is achieved. The remaining shares granted to management were service based and vest over four years. For the years ended December 31, 2005 and 2004, the Company granted approximately 0.5 million and 0.1 million shares, respectively, of restricted common stock to officers, directors and other management. The restrictions on the restricted stock granted to the Company's officers during 2005 lapse as follows: (i) restrictions covering one-half of the shares will lapse 25% each year over a four-year period commencing with the grant date; and (ii) the restrictions covering the remaining one-half of the shares have a four-year cliff provision with the possibility for acceleration of the removal of restrictions for 25% of this half of the grant annually upon the achievement of certain annual revenue, EBITDA and strategic goals set by the Board of Directors. The restrictions on restricted stock granted to the Company's officers during 2004 lapse ratably over four years, while all restrictions on the restricted stock granted to the Company's directors lapse over a one-year period.

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

*Stock Options.* The Company grants options to employees and non-employee directors under its amended and restated 2001 Equity Incentive Plan (the 2001 Plan) and previously granted options under the 1998 Stock Incentive Plan and the 1996 Non-Employee Directors Stock Option Plan. The 1998 and

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 4. Stockholders Equity (Continued)**

1996 Plans were terminated at the time of adoption of the 2001 Plan, but the terminated Plans continue to govern outstanding options granted thereunder. The Company has stock options outstanding which were issued under those various equity incentive plans to certain employees and directors, which have terms ranging up to 10 years, have exercise prices ranging from \$2.25 to \$14.50, and generally vest over four years. As of December 31, 2006, 0.8 million shares remained available for grant under the 2001 Plan.

*Employee Stock Purchase Plan.* Under the Company's 1983 Employee Stock Purchase Plan (the "ESPP"), full-time employees are allowed to purchase common stock through payroll deductions (which cannot exceed 10% of the employee's compensation) at the lower of 85% of fair market value at the beginning or end of each six-month option period. As of December 31, 2006, 825,136 shares had been sold under the Plan, leaving 174,684 shares available for future issuance.

*Share Repurchase Program.* In May 2005, the Company's Board of Directors authorized the Company to repurchase up to \$25.0 million in shares of its common stock. Shares of the Company's common stock repurchased under this program will no longer be deemed outstanding upon repurchase and will be returned to the pool of authorized shares. This repurchase program will expire no later than March 9, 2009 unless extended by the Board of Directors. As of December 31, 2006, the Company had repurchased approximately 1.3 million shares under this program, at a cost of approximately \$11.6 million. In March 2007, the Company's Board of Directors authorized the Company to repurchase up to an additional \$25 million in shares of the Company's common stock. See Note 10.

*Shares Reserved for Future Issuance.* At December 31, 2006, approximately 3.4 million shares of common stock were reserved under the Company's equity incentive plans, and 0.2 million were reserved for purchases under the ESPP.

**Note 5. Stock-Based Compensation**

Prior to January 1, 2006, the Company followed APB Opinion No. 25, and related Interpretations, in accounting for its employee and director stock options. Under APB No. 25, because the exercise price of the Company's employee and director stock options equaled or exceeded the estimated market price of the underlying stock on the date of grant, no compensation expense was recognized.

Effective January 1, 2006, the Company began recording compensation expense associated with stock options in accordance with SFAS No. 123(R). The Company has adopted the modified prospective transition method provided under SFAS No. 123(R) and, as a result, has not retroactively adjusted results from prior periods. Under this transition method, compensation expense associated with stock options recognized in the fiscal year 2006 includes: 1) expense related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123; and 2) expense related to all stock option awards granted subsequent to January 1, 2006 based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R).

The Company's net earnings for the year ending December 31, 2006 includes \$2.1 million and \$1.3 million of compensation expense related to stock option awards ( "stock options" ) and restricted stock awards ( "stock awards" ), respectively. The compensation expense related to the Company's stock-based compensation plans is included in the statement of operations for the year ended December 31, 2006 as

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 5. Stock-Based Compensation (Continued)**

follows: cost of sales of \$0.3 million, research and development of \$0.6 million, sales and marketing of \$0.5 million and general and administrative of \$2.0 million. The adoption of FAS No. 123(R) decreased net earnings for the year ended December 31, 2006 by approximately \$2.1 million. As a result, basic and diluted earnings per share for the year ended December 31, 2006 were reduced by \$0.06 per share.

As previously announced, the Company's Chief Financial Officer, Paul E. Landers, will retire from the Company effective March 31, 2007. In December 2006, the Company entered into an employment agreement with Mr. Landers in which the vesting on a portion of his outstanding equity grants will be accelerated as of his retirement date. This requires modification accounting of these grants under SFAS No. 123(R) and will result in stock compensation expense of approximately \$0.4 million during the first quarter of 2007. The expense associated with this for 2006 was immaterial.

Compensation costs capitalized to inventory and compensation expense related to the Company's ESPP were not material for the year ended December 31, 2006.

**Stock Options**

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

	<b>Year ended</b>		
	<b>December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Risk-free interest rate	4.64 %	4.4 %	3.4 %
Expected option life (in years)	4.55	4.6	5.3
Volatility	0.75	0.80	0.82
Dividend Rate	0 %	0 %	0 %

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

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 5. Stock-Based Compensation (Continued)**

The Company's determination of fair value is affected by the Company's stock price as well as a number of assumptions that require judgment. The weighted-average fair value per share was \$6.76, \$3.54 and \$4.23 for options granted during the years ended December 31, 2006, 2005 and 2004, respectively. The total intrinsic value was \$5.0 million, \$4.0 million and \$8.4 million for options exercised during the years ended December 31, 2006, 2005 and 2004, respectively. As of December 31, 2006, total unrecognized compensation cost related to stock options was approximately \$2.9 million and the related weighted-average period over which it is expected to be recognized is approximately 1.9 years. The maximum contractual term of the Company's stock options is 10 years.

A summary of the status of stock option activity for the year ended December 31, 2006 is as follows (in thousands, except price data):

	Number of Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2003	4,479	\$ 4.51		
Granted	1,567	5.69		
Exercised	(1,387 )	4.45		
Cancelled	(819 )	5.71		
Outstanding at December 31, 2004	3,840	4.84		
Granted	291	5.45		
Exercised	(1,376 )	4.27		
Cancelled	(302 )	6.07		
Outstanding at December 31, 2005	2,453	5.09		
Granted	301	10.95		
Exercised	(666 )	5.13		
Cancelled	(54 )	7.81		
Outstanding at December 31, 2006	2,034	\$ 5.87	7.21	\$ 15,746
Vested and expected to vest at December 31, 2006	1,916	\$ 5.78	7.14	\$ 15,023
Exercisable at December 31, 2006	1,104	\$ 4.96	6.38	\$ 9,568
Available for future grant at December 31, 2006	758			

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 5. Stock-Based Compensation (Continued)**

The following table summarizes information about outstanding and exercisable options at December 31, 2006:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Options Outstanding	Weighted-Average Remaining Contractual Life in Years	Weighted-Average Exercise Price	Options Exercisable	Weighted Average Exercise Price of Options Exercisable	
\$ 2.25      \$ 3.38	151,497	4.63	\$ 3.18	138,261	\$ 3.18	
\$ 3.46      \$ 3.46	450,000	7.64	3.46	253,125	3.46	
\$ 3.54      \$ 3.99	248,189	6.93	3.81	139,782	3.84	
\$ 4.00      \$ 4.98	204,629	6.85	4.36	118,966	4.45	
\$ 5.04      \$ 5.85	337,601	6.77	5.63	258,851	5.56	
\$ 6.01      \$ 7.50	227,256	6.69	6.95	127,896	6.90	
\$ 7.53      \$ 11.90	254,374	8.33	10.32	65,529	11.31	
	\$12.23	147,000	9.22	0	0.00	
	\$13.09	8,000	8.94	2,000	13.09	
	\$14.50	5,000	9.81	0	0.00	
\$ 2.25      \$ 14.50	2,033,546	7.21	\$ 5.87	1,104,410	\$ 4.95	

**Stock Awards**

The fair value of stock awards is determined based on the closing market price of the Company's common stock on the grant date. Compensation expense for stock awards is measured at the grant date and recognized ratably over the vesting period. Stock awards granted in 2004 are service based and lapse ratably over a four year vesting period. For stock awards granted in 2005, vesting is based on both the service period as well as the achievement of the Company's 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 March 2006 were performance based and vesting is tied to achievement of the Company's 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. A significant portion of the Company's stock grants contains performance-based 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. The measurement 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 grant. 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.

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 5. Stock-Based Compensation (Continued)**

A summary of the status of stock awards activity for the year ended December 31, 2006 is as follows (in thousands, except price data):

	Shares	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2004		\$
Granted	63	6.95
Vested	(22)	7.49
Forefeited		
Nonvested at December 31, 2004	41	\$ 6.68
Granted	539	4.36
Vested	(27)	6.26
Forefeited		
Nonvested at December 31, 2005	553	\$ 4.44
Granted	160 *	12.05
Vested	(198)	4.55
Forefeited	(24)	6.90
Nonvested at December 31, 2006	491	\$ 6.76

\* Stock awards granted do not include 112,000 performance-based shares which are based on specific goals to be determined in the future.

Stock-based compensation expense related to stock awards outstanding was approximately \$1.3 million, \$0.6 million, and \$0.1 million during the years ended December 31, 2006, 2005 and 2004, respectively. As part of the adoption of FAS No. 123(R), the deferred compensation costs of \$1.9 million at December 31, 2005 were reclassified as a reduction of additional paid-in capital beginning January 1, 2006. The total amount of unrecognized compensation cost related to nonvested stock awards as of December 31, 2006 was approximately \$3.7 million, which is expected to be recognized over a weighted-average period of approximately 2.2 years.

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 5. Stock-Based Compensation (Continued)**

The pro forma impact to net loss as if the fair value-based method had been applied to all stock options and stock awards for the years ended December 31, 2005 and 2004 is as follows (in thousands, except per share amounts):

	Year ended December 31, 2005	Year ended December 31, 2004
Net loss, as reported	\$ (9,259 )	\$ (6,287 )
Add: Stock-based compensation expense included in reported net loss, net of related tax effects	595	84
Deduct: Stock-based compensation expense determined under fair value-based method for all awards, net of related tax effects	(2,786 )	(3,599 )
Pro forma net loss	\$ (11,450 )	\$ (9,802 )
Basic and diluted loss per share as reported	\$ (0.28 )	\$ (0.20 )
Basic and diluted loss per share pro forma	\$ (0.35 )	\$ (0.31 )

**Note 6. Commitments and Contingencies**

*Leases.* The Company leases its facilities and certain equipment. Commitments for minimum rentals under non-cancelable leases at the end of 2006 are as follows (in thousands):

	Operating Leases	Capital Leases
Years ending December 31,		
2007	\$ 1,337	\$ 1,377
2008	1,479	1,404
2009	1,640	1,432
2010	27	1,461
2011	18	1,490
Thereafter		4,653
Total minimum lease payments	\$ 4,501	11,817
Less amount representing interest		(3,378 )
Present value of capital lease payments		8,439
Less current portion		(675 )
Long-term obligations under capital leases		\$ 7,764

At December 31, 2006, assets under capital leases included in property and equipment totaled \$12.9 million with accumulated amortization of \$7.9 million.

Rent expense under operating leases totaled approximately \$1.4 million, \$1.4 million and \$1.5 million for the years ended December 31, 2006, 2005 and 2004, respectively.

The Company had a purchase commitment for inventory components of \$2.2 million associated with an asset purchase and license agreement.

During December 1999, the Company completed a sale and leaseback transaction of its San Diego facility. The facility was sold for \$15.0 million, of which \$3.8 million was capital contributed by the

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 6. Commitments and Contingencies (Continued)**

Company. The Company's lease for its 78,000 square foot facility in San Diego, CA is for 15 years, with options to extend the lease for up to two additional five-year periods. The sale was an all cash transaction, netting the Company approximately \$7.0 million. The Company is a 25% limited partner in the partnership that acquired the facility. The transaction was deemed a financing transaction under SFAS No. 98 *Accounting for Sales of Real Estate*. As such, the assets sold remain on the books of the Company and will continue to be depreciated over the estimated useful life. The Company made lease payments of approximately \$1.3 million for each of the years ended December 31, 2006, 2005 and 2004.

**Contracts**

The Company has entered into various licensing agreements which require royalty payments based on specified product sales. These agreements encompass the majority of the Company's products, and range in expiration through 2019. In addition, as part of the Company's litigation settlement with Inverness Medical Innovations, Inc. (IMA) in the first quarter of 2005, the Company entered into a royalty agreement with IMA during 2005, which requires ongoing royalty payments of 8.5% on the majority of its current products. Royalty expenses, which are charged to cost of sales under these licensing agreements, totaled \$9.6 million, \$7.1 million and \$5.6 million for the years ended December 31, 2006, 2005 and 2004, respectively. As of December 31, 2006 and 2005, \$3.6 million and \$3.4 million, respectively, were recorded as accrued royalties in the accompanying consolidated balance sheets. During the fourth quarter of 2006, the Company entered into a cross-licensing agreement with another company and paid \$6.5 million which amount is being amortized on a straight-line basis through December 2008. The Company believes it will continue to incur substantial royalty expenses relating to future sales of its products.

**Legal**

The Company is involved in litigation matters from time to time in the ordinary course of business. Management believes that any and all such other actions, in the aggregate, will not have a material adverse effect on the Company. The Company also maintains insurance, including coverage for product liability claims, in amounts which management believes appropriate given the nature of its business.

**Note 7. Industry and Geographic Information**

The Company operates in one reportable segment. Sales to customers outside the U.S. totaled 20%, 26%, and 29% of net sales for the years ended December 31, 2006, 2005 and 2004, respectively. As of December 31, 2006 and 2005, balances due from foreign customers, in U.S. dollars, were \$5.5 million and \$6.3 million, respectively.

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

Customer:	Year ended December 31,		
	2006	2005	2004
A	18 %	18 %	16 %
B	11 %	17 %	13 %
C	13 %	15 %	15 %
D	17 %	14 %	12 %



**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 7. Industry and Geographic Information (Continued)**

As of December 31, 2006 and 2005, accounts receivable from individual customers with balances due in excess of 10% of total accounts receivable totaled \$11.3 million and \$9.3 million, respectively.

The following presents long-lived assets and net sales by geographic territory (in thousands):

	Long-lived assets December 31,		Net sales year ended December 31,		
	2006	2005	2006	2005	2004
United States operations					
Domestic	\$ 20,058	\$ 19,557	\$ 83,692	\$ 65,863	\$ 53,872
Foreign			21,040	22,868	21,733
Foreign operations					467
Total	\$ 20,058	\$ 19,557	\$ 104,732	\$ 88,731	\$ 76,072

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

	Year ended December 31,		
	2006	2005	2004
Influenza	\$ 42,792	\$ 33,412	\$ 25,661
Group A Strep	24,138	19,412	16,502
Pregnancy	19,674	19,292	16,499
Bone markers	4,590	5,241	4,989
H. pylori	3,357	3,015	3,032
Auto-immune and Complement	2,602	2,259	2,435
Other products	7,579	6,100	6,954
	\$ 104,732	\$ 88,731	\$ 76,072

**Note 8. Employee Benefit Plan**

The Company has a defined contribution 401(k) plan (the 401(k) Plan ) covering all employees who are eligible to join the 401(k) Plan upon employment. Employee contributions are subject to a maximum limit by federal law. This plan includes an employer match of 50% on the first 6% of pay contributed by the employee. The Company contributed approximately \$0.5 million to the 401(k) Plan during the year ended December 31, 2006, and \$0.4 million for each of the years ended December 31, 2005 and 2004.

**Note 9. Discontinued Operations**

In the accompanying financial statements, the Company's urinalysis and ultrasonometer businesses are reported as discontinued operations under SFAS No. 144. The Company discontinued all operations of its ultrasonometer business during the fourth quarter of 2004, and during the second quarter of 2005, the Company sold certain assets of the urinalysis business for \$0.5 million. Accordingly, the operations of both businesses have been classified as discontinued operations in the statements of operations for all periods presented. During the fourth quarter of 2006, the Company finalized its open tax audits in Germany and recognized a non-cash gain on discontinued operations of approximately \$0.8 million associated with certain remaining balance sheet credits of the urinalysis operation sold during 2005.

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 9. Discontinued Operations (Continued)**

During the fourth quarter of 2006, the Company recognized non-cash income of approximately \$1.3 million associated with certain remaining balance sheet credits of its foreign entities. These amounts were recorded as a gain on discontinued operations of \$0.8 million related to the prior divestiture of the Company's urinalysis business, and other income of \$0.5 million related to the previous closure of other foreign operations.

Operating results of the urinalysis and ultrasonometer businesses are presented in the following table (in thousands):

	<b>December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Net sales from discontinued operations			
Urinalysis	\$	\$ 572	\$ 1,573
Ultrasonometer			263
Total	\$	\$ 572	\$ 1,836
Gain (loss) from discontinued operations, net of taxes			
Loss from operations			
Urinalysis	\$ 797	\$ (835 )	\$ (1,823 )
Ultrasonometer		(97 )	(80 )
	797	(932 )	(1,903 )
Gain (loss) on asset impairment			
Urinalysis			(5,193 )
Ultrasonometer			(775 )
			(5,968 )
Total	\$ 797	\$ (932 )	\$ (7,871 )

**Note 10. Subsequent Events**

As of March 9, 2007, the Company repurchased approximately 0.8 million shares of common stock during the first fiscal quarter of 2007 at a cost of approximately \$8.0 million under its May 2005 share repurchase program. In March 2007, the Company's Board of Directors authorized the Company to repurchase up to an additional \$25 million in shares of its common stock under such share repurchase program. In addition, the Board of Directors extended the Company's share repurchase program to March 9, 2009.

**QUIDEL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 11. Quarterly Financial Information (unaudited)**

	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Total Year</b>
<b>2006</b>					
Total revenues	\$ 27,050	\$ 16,471	\$ 23,720	\$ 38,774	\$ 106,015
Gross profit	16,159	7,532	13,092	23,131	59,914
Total cost and expenses	21,868	20,679	21,721	27,913	92,181
Earnings (loss) from continuing operations	5,328	(4,049 )	2,143	17,499	20,921
Gain from discontinued operations, net of taxes				797	797
Net earnings (loss)	5,328	(4,049 )	2,143	18,296	21,718
Basic earnings (loss) per share:					
Continuing operations	0.16	(0.12 )	0.07	0.53	0.63
Discontinued operations	0.00	0.00	0.00	0.02	0.02
Net earnings (loss)	0.16	(0.12 )	0.07	0.56	0.66
Diluted earnings (loss) per share:					
Continuing operations	0.15	(0.12 )	0.06	0.51	0.61
Discontinued operations	0.00	0.00	0.00	0.02	0.02
Net earnings (loss)	0.15	(0.12 )	0.06	0.54	0.63
<b>2005</b>					
Total revenues	\$ 22,666	\$ 14,823	\$ 20,032	\$ 34,778	\$ 92,299
Gross profit	13,157	6,778	10,413	21,282	51,630
Total cost and expenses	37,310	16,858	18,704	24,717	97,589
Earnings (loss) from continuing operations	(17,655 )	(1,255 )	816	9,767	(8,327 )
Loss from discontinued operations, net of taxes	(196 )	(455 )	(116 )	(165 )	(932 )
Net earnings (loss)	(17,851 )	(1,710 )	700	9,602	(9,259 )
Basic earnings (loss) per share:					
Continuing operations	(0.55 )	(0.04 )	0.02	0.30	(0.26 )
Discontinued operations	(0.01 )	(0.01 )	(0.00 )	(0.00 )	(0.03 )
Net earnings (loss)	(0.56 )	(0.05 )	0.02	0.29	(0.28 )
Diluted earnings (loss) per share:					
Continuing operations	(0.55 )	(0.04 )	0.02	0.28	(0.26 )
Discontinued operations	(0.01 )	(0.01 )	(0.00 )	(0.00 )	(0.03 )
Net earnings (loss)	(0.56 )	(0.05 )	0.02	0.28	(0.28 )

## SCHEDULE II

**QUIDEL CORPORATION**  
**CONSOLIDATED VALUATION AND QUALIFYING ACCOUNTS**  
(in thousands)

Description	Additions Balance at beginning of period	Charges to costs and expenses(1)	Charges to other accounts	Deductions(2)	Balance at end of period
Year ended December 31, 2006:					
Accounts Receivable Allowance	\$ 1,082	\$ 1,167		\$ 1,458	\$ 791
Year ended December 31, 2005:					
Accounts Receivable Allowance	\$ 1,308	\$ 1,693		\$ 1,919	\$ 1,082
Year ended December 31, 2004:					
Accounts Receivable Allowance	\$ 2,006	\$ 1,029		\$ 1,727	\$ 1,308

(1) The charges represent reductions to reserves associated primarily to accruals for early payment discounts and bad debt.

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

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
3.1	Certificate of Incorporation, as amended. (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on February 26, 1991.)
3.2	Amended and Restated Bylaws. (Incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K dated November 8, 2000.)
4.1	Certificate of Designations of Series C Junior Participating Preferred Stock as filed with the State of Delaware on December 31, 1996 (Incorporated by reference to Exhibit 1(A) to the Registrant's Registration Statement on Form 8-A filed on January 14, 1997.)
4.2	Amended and Restated Rights Agreement dated as of December 29, 2006 between Quidel Corporation and American Stock Transfer and Trust Company, as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on January 5, 2007.)
10.1(1)	Registrant's 1983 Employee Stock Purchase Plan, as amended. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 25, 2005.)
10.2(1)	Registrant's 1990 Employee Stock Option Plan. (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1990.)
10.3(1)	Registrant's 1996 Non-Employee's Director Plan. (Incorporated by reference to Registrant's Proxy Statement filed on September 27, 1996.)
10.4(1)	Registrant's 1998 Stock Incentive Plan. (Incorporated by reference to Registrant's Proxy Statement filed on July 8, 1998.)
10.5(1)	Registrant's Amended and Restated 2001 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.2 to Registrant's Form 8-K filed on August 23, 2005.)
10.6(1)	Form of Restricted Stock/Stock Option Agreement used in connection with the Registrant's Amended and Restated 2001 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.6 to the Registrant's Form 10-Q for the quarter ended September 30, 2004.)
10.7	Settlement Agreement effective April 1, 1997 between the Registrant and Becton, Dickinson and Company. (Incorporated by reference to Exhibit 10.18 to the Registrant's Form 10-K for the year ended March 31, 1997.)
10.8	Rosenstein License Agreement effective April 1, 1997 between the Registrant and Becton, Dickinson and Company. (Incorporated by reference to Exhibit 10.20 to the Registrant's Form 10-K for the year ended March 31, 1997.)
10.9	Form of Purchase and Sale Agreement and Escrow Instructions. (Incorporated by reference to Exhibit 10.6 to the Registrant's Form 8-K filed on January 4, 2000.)
10.10	Form of Single Tenant Absolute Net Lease. (Incorporated by reference to Exhibit 10.7 to the Registrant's Form 8-K filed on January 4, 2000.)
10.11	Form of Indemnification Agreement Corporate Officer and/or Director. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed August 23, 2005.)
10.12(1)	Change in Control Agreement dated February 28, 2003 between the Registrant and Paul E. Landers. (Incorporated by reference to Exhibit 10.33 to the Registrant's Form 10-Q, for the quarter ended March 31, 2003.)

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- 10.13(1) Amendment No. 1 to Change in Control agreement dated February 28, 2003 between the Registrant and Paul E. Landers. (Incorporated by reference to Exhibit 10.30 to the Registrant's Form 10-Q for the quarter ended June 30, 2004.)
- 10.14(1) Change in Control Agreement dated April 13, 2003 between the Registrant and Mark E. Paiz. (Incorporated by reference to Exhibit 10.34 to the Registrant's Form 10-Q for the quarter ended March 31, 2003.)
- 10.15(1) Amendment No. 1 to Change in Control agreement dated April 13, 2003 between the Registrant and Mark E. Paiz. (Incorporated by reference to Exhibit 10.32 to the Registrant's Form 10-Q for the quarter ended June 30, 2004.)
- 10.16(1) Change in Control Agreement dated July 19, 2004 between the Registrant and Scot M. McLeod. (Incorporated by reference to Exhibit 10.34 to the Registrant's Form 10-Q for the quarter ended June 30, 2004.)
- 10.17(1) Change in Control Agreement dated July 19, 2004 between the Registrant and Michael J. Beck. (Incorporated by reference to Exhibit 10.35 to the Registrant's Form 10-Q for the quarter ended June 30, 2004.)
- 10.18(1) Stock Option Agreement effective August 20, 2004 between the Registrant and Caren L. Mason. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on August 26, 2004.)
- 10.19(1) Employment Agreement dated as of August 20, 2004 between the Registrant and Caren L. Mason. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on August 26, 2004.)
- 10.20(1) Change in Control Agreement dated August 20, 2004, between the Registrant and Caren L. Mason. (Incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed on August 26, 2004.)
- 10.21(1) Employment Offer Letter dated as of October 26, 2004 between Registrant and Thomas J. Foley, Ph.D. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on November 2, 2004.)
- 10.22(1) Change in Control Agreement effective as of November 8, 2004 between Registrant and Thomas J. Foley, Ph.D. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on November 2, 2004.)
- 10.23(1) Employment Offer Letter, entered into on June 13, 2005, between Registrant and Robert J. Bujarski, J.D. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on June 17, 2005.)
- 10.24(1) Agreement Re: Change in Control, entered into on February 14, 2007, between Registrant and Robert J. Bujarski, J.D. (Incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed on February 20, 2007.)
- 10.25(1) Employment Offer Letter, entered into on December 18, 2006, between Quidel Corporation and John M. Radak. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 3, 2007.)
- 10.26(1) Agreement Re: Change in Control, entered into on December 18, 2006, between Quidel Corporation and John M. Radak. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on January 3, 2007.)
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- 10.27(1) Annual Base Salary for the Company's Executive Officers effective as of March 5, 2007. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on February 20, 2007.)
  - 10.28(1) 2006 Non-Employee Director Compensation Program. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 23, 2006.)
  - 10.29(1) Form of 2006 Non-Employee Director Stock Option Agreement. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on May 23, 2006.)
  - 10.30(1) Registrant's 2006 Cash Bonus Awards. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on February 20, 2007.)
  - 10.31(1) Executive officers' 2006 Equity Award Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on March 23, 2006.)
  - 10.32(1) Form of 2006 Executive Officer Restricted Stock Award Agreement. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on March 23, 2006.)
  - 10.33 Credit Agreement by and among Quidel Corporation, as Borrower, each lender from time to time party thereto (collectively, Lenders and individually, a Lender) and Bank of America, N.A., as Agent and L/C Issuer, dated as of January 31, 2005. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on March 14, 2005.)
  - 10.34 Security Agreement by and among Quidel Corporation, as Borrower, direct and indirect domestic subsidiaries of Borrower, each additional grantor that may become a party thereto and Bank of America, N.A., as Agent, dated as of January 31, 2005. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on March 14, 2005.)
  - 10.35 First Amendment to Credit Agreement, dated as of June 24, 2005, by and among Registrant, as Borrower, certain subsidiaries of the Company, each lender from time to time a party thereto and Bank of America, N.A., as Agent and L/C Issuer. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on July 20, 2005.)
  - 10.36 Second Amendment to Credit Agreement, dated as of September 1, 2005, by and among Registrant, as Borrower, certain subsidiaries of the Company, each lender from time to time a party thereto and Bank of America, N.A., as Agent and L/C Issuer. (Incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-Q filed on November 8, 2005).
  - 10.37 Settlement Agreement dated April 27, 2005 between the Registrant and Inverness Medical Innovations, Inc. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 3, 2005.)
  - 10.38(1) Consulting Agreement, dated December 29, 2006, between Registrant and Paul E. Landers. (Incorporated by reference to the Registrant's Form 8-K filed on January 5, 2007.)
  - 21.1\* Subsidiaries of the Registrant.
  - 23.1\* Consent of Independent Registered Public Accounting Firm.
  - 31.1\* Certification by Chief Executive Officer of Registrant pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
  - 31.2\* Certification by Principal Financial and Accounting Officer of Registrant pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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32.1\* Certifications by Chief Executive Officer and Principal Financial and Accounting Officer of Registrant pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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\* Filed herewith

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

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