QUIDEL CORP /DE/
Form 10-K
March 09, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2005

OR

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

For the transition period from N/A to

Commission file number: 0-10961

QUIDEL CORPORATION

(Exact name of registrant as specified in its charter)

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

858-552-1100

(Registrant s telephone number, including area code)

Not Applicable

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

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.001 par value, and accompanying

Preferred Shares Purchase Rights

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes o No x

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

Yes o No x

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 x No o

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

o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 o Accelerated filer x Non-accelerated filer o

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

Yes o No x

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant was $168,269,492 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 1, 2006, 33,902,945 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 2006 Annual Meeting of Stockholders (to be held on May 17, 2006) are incorporated by reference into Part III, Items 10, 11, 12, 13 and 14 of this Annual Report on Form 10-K.

A Warning About Forward Looking Statements

This Annual Report on Form 10-K contains forward looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those 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, intellectual property, product liability, environmental and other litigation, required patent license fee payments not currently reflected in our costs, seasonality, the length and severity of cold and flu seasons, uncertainty surrounding the detection of H5N1 in human specimens, adverse changes in the competitive and economic conditions in domestic and international markets, actions of our major distributors, manufacturing and production delays or difficulties, the uncertainties associated with product development efforts, adverse actions or delays in product reviews by the United States Food and Drug Administration (the FDA), 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, 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 and Recent Developments

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 enjoy 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 the U.S., we lead the market in several professional POC product categories. This leadership position includes an estimated 66%, 50% and 46% market share in influenza, pregnancy and Group A Strep test products, respectively, as of December 31, 2005. 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 research markers and products sold by SPG have a significant market share, and 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.

In September 2005, we entered into an Asset Purchase and License Agreement (the Asset Purchase Agreement) with Alfa Scientific Designs, Inc. (Alfa), in which we acquired an immunochemical fecal occult blood test (the iFOB test) product and obtained a license for certain intellectual property relating to the iFOB test product for $5.0 million. The iFOB test is FDA-cleared and waived by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and is being marketed to healthcare professionals as the QuickVue® iFOB test. We believe the iFOB test category represents a large market opportunity for us, as over 50 million fecal occult blood (FOB) tests are sold annually through medical and surgical distributors in the U.S. In addition, current Medicare reimbursement rates for iFOB tests are significantly higher than the current guaiac based FOB tests, and have no dietary restrictions while exhibiting higher analytical sensitivity. We launched our iFOB test in December 2005 and expect independent clinical validation and economic studies under our QVB program related to our iFOB test to further establish this product as an important colon cancer screening tool. Under the terms of the Asset Purchase Agreement, we made an initial cash payment of $2.5 million upon closing, while $1.5 million is expected to be paid during the first quarter of 2006, with the remaining $1.0 million to be paid during the third quarter of 2006 upon transfer of complete product manufacturability. In our transition to complete manufacturability, Alfa will supply iFOB test product components to us. Under the Asset Purchase Agreement, we currently have firm purchase commitments of approximately $2.7 million related to product component purchases from Alfa. As of December 31, 2005, we have approximately $5.0 million recorded as an intangible asset in the accompanying balance sheet, while the remaining portion to be paid of $2.5 million has been recorded in other current liabilities in the accompanying balance sheet. The intangible asset is being amortized over a period of five years.

In November 2005, we entered into a net cross-license agreement with Dade Behring, Inc. and Dade Behring Marburg GmbH (collectively Dade) whereby the parties agreed to cross-license their respective patent portfolios solely directed to immunochromatographic lateral flow test strip devices with respect to current products and based on the terms of the cross-license agreement. Per the terms of the cross-license agreement, we made a one-time payment of $1.5 million to Dade during the fourth quarter of 2005 as additional consideration for the fully paid-up net cross-license, and the amount will be amortized through August 2006.

As part of our QVB commitment, we announced the results of a clinical study conducted to further validate the performance of our QuickVue® Influenza A+B test. The study was completed in Australia during that continent s flu season from July through September 2005 and showed 96% sensitivity (true positive identification) and 97% specificity (true negative identification) in detecting type A influenza when final results were validated using the RT PCR (reverse transcription-polymerase chain reaction) method for laboratory accuracy. The protocol of the clinical study was approved in advance by Australia s National Research and Evaluation Ethics Committee and was conducted at general practitioner offices across New South Wales. The clinical data reinforces the analytical study findings from the University of Rochester Medical Center, announced in May 2005, which demonstrated that our test had the highest sensitivity, 95% of the time, was the easiest to use and provided the most rapid time to result compared with certain competing rapid tests.

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. We believe the FDA clearance for our label with the latest clinical studies is significant as our influenza tests with nasal swab specimen collection are uniquely positioned for ease-of-use and results in less than 10 minutes. In addition, the label was also updated to include the fact that our QuickVue Influenza A+B test has been shown to detect cultured avian influenza viruses, including avian Influenza A subtype H5N1 virus. However, our label indicates the ability of the QuickVue Influenza A+B test to detect influenza A in patients infected with H5N1 has not been established.

In the accompanying financial statements, our urinalysis and ultrasonometer businesses are reported as discontinued operations under SFAS No. 144 Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS No 144). We discontinued all operations of our ultrasonometer business during the fourth quarter of 2004, and 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. The loss from discontinued operations, net of taxes, was $0.9 million, $7.9 million and $1.7 million for the years ended December 31, 2005, 2004 and 2003, respectively.

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

Business Strategy

We believe that the trend among healthcare providers to adopt POC testing is increasing, 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 which supports the adoption of rapid POC testing;

- continue to focus on strengthening 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 assisted by the expansion of our sales organization to assure exceptional physician satisfaction;

- drive profit through further refinement of industry leading manufacturing efficiencies and productivity improvements. We will seek to focus exclusively on profitable products and markets and expect to create exceptional competency in new product development process management;

- identify and commercialize new markers, products and collaborations in oncology and 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 development of novel therapeutics to the diagnosis of disease and monitoring of therapy. We believe opportunistic near term development is possible in the areas of bone health and oncology;

- complete the full-scale manufacturability feasibility study for our Layered Thin Film (LTF) proprietary technology. Continue parallel pathways for development and acquisition of qualitative and quantitative technology platforms that meet economic and clinical validation criteria for additional targeted disease states; and

- establish business development and strategic assessment as a leading core competency, and aggressively pursue licensing, acquisition and partnership opportunities.

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 immunodiagnostics 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 CLIA waiver. In 2005, an estimated 99,000, or 55%, of physician office laboratories had a CLIA waiver.

Technology

Our immunoassay development program is evaluating a variety of leading technology and product licensing opportunities from a number academic research departments. These opportunities are intended to complement our continuing work on the LTF platform and give us a broader selection of platforms from which to develop qualitative and quantitative single assay and panel assays required for an assortment of customer applications.

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.

Products

We derive a significant portion of our net sales from three product families. For the years ended December 31, 2005, 2004 and 2003, we derived approximately 82%, 77% and 79%, 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, 2005, 2004 and 2003, export sales to unaffiliated customers constituted approximately 26%, 29% and 41%, 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. This diagnostic test was developed through a funded collaboration with a third party, as an aid in the diagnosis and treatment of influenza at the POC. The test is a rapid, qualitative test for the detection of the viral antigens of influenza type A and B, the two most common types of the influenza virus. The test first 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. Influenza product sales represented approximately 38%, 34% and 41% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively.

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. Net sales of Group A Strep products represented approximately 22%, 22% and 19% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively.

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 in August 2000. *H. pylori* tests accounted for approximately 3%, 4% and 3% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively.

Mononucleosis. Infectious Mononucleosis can be severely debilitating to immune suppressed groups, including the elderly, if not diagnosed and treated promptly. Net sales of mononucleosis tests represented approximately 2%, 2% and 1% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively.

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. Pregnancy test sales, primarily consisting of tests sold to physicians and other healthcare organizations, represented

approximately 22%, 22% and 19% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively.

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. Net sales of Chlamydia tests represented approximately 1%, 2% and 1% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively.

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. Two products for the clinical evaluation of infectious vaginitis, a test for pH and amines and a test for *Gardnerella Vaginalis*, were launched in July 2002 utilizing our LTF technology. They represent our first rapid diagnostic tests for infectious vaginitis. Net sales of our BV tests represented approximately 1% of our net sales for each of the years ended December 31, 2005, 2004 and 2003.

Bone Health and Oncology

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. The National Osteoporosis Foundation (the NOF) estimates that 10 million people in the U.S. have osteoporosis, and an additional 34 million are at significantly increased risk due to low bone mass. Osteoporosis is responsible for more than 1.5 million fractures annually in the U.S. Half of women aged 50 years and older will experience a fracture in their remaining lifetime and, according to the NOF, 24% of women suffering a hip fracture will die within the first year. A key set of parameters in the monitoring of osteoporosis, both before and after therapy, are biochemical markers of bone metabolism. As a global leader in the field of bone markers, we produce both clinical and research products for the assessment of osteoporosis and the evaluation of bone resorbtion/formation, which, including our metabolic bone markers, are used by physicians to monitor the effectiveness of therapy in pharmaceutical and related research. Net sales of biochemical bone markers represented approximately 6%, 7% and 6% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively.

Oncology. Accurate early diagnosis of specific cancers is a critical diagnostic need. YKL-40 is a low molecular weight serum protein secreted by a variety of cell types. Under normal conditions, serum and plasma levels of YKL-40 are extremely low. In certain, specific diseases and states, including cancer, levels of YKL-40 can increase dramatically. Our SPG is investigating the potential of YKL-40 as an oncology marker. Net sales of our YKL-40 products represented approximately $0.2 million for the year ended December 31, 2005 and $0.1 million for both the years ended December 31, 2004 and 2003. These amounts are reported as part of our other products noted below.

Other Products

The remaining 5%, 6% and 9% of net sales for the three years ended December 31, 2005, 2004 and 2003 include veterinary products, oncology, and clinical laboratory and research tests used in the measurement of circulating immune complexes, complement deficiencies and complement activation.

Newly Introduced Products and Products and Processes Under Development

Newly Introduced Products

- *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.

Products Under Development

- *RSV Test*: We are conducting clinical testing of our new immunoassay for Respiratory Syncitial Virus (RSV) and expect to launch this product in late 2006. 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.

- *Novel Metra® Brand Bone Marker Assays*: We are extending the scope of our Metra® brand to include new immunoassays for a variety of bone health analytes of research and diagnostic interest. We expect to launch these to the research community in 2006. We are also developing clinical diagnostic applications of existing tests that may provide us with assays for the POC market downstream.

Processes Under Development

- *Flu A + B*: We are transferring our QuickVue Influenza A + B test onto our new, highly automated manufacturing process that helps ensure a superior quality product. We expect this product to be produced utilizing this process during the second half of 2006.

Seasonality

Sales of our Group A Strep and influenza 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, 2005, 2004 and 2003, net sales in the first and fourth quarters have combined for 63%, 65% and 61%, 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, 2005, 2004 and 2003, sales of our influenza and Group A Strep products accounted for 60%, 55% and 60%, respectively, of net sales. 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 their 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 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 via our SPG, and 3) products developed under collaborations with other companies for new and existing markets. Research and development expenses were approximately $12.8 million, $11.3 million and $8.5 million for the years ended December 31, 2005, 2004 and 2003, respectively. Expenses related to

customer sponsored research activities for the year ended December 31, 2004 was $0.6 million. There were no significant customer sponsored research activities during the years ended December 31, 2005 and 2003. During the second quarter of 2005, our joint development agreement with a Fortune 500 company 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 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 need 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 lower than domestic sales. Part of this difference is due to the POC market being more developed in the U.S. relative to the overall IVD market in other countries.

During 2005, we invested in several key areas: baselining our brand equity, more in depth analysis related to voice of the customer (VOC), expanding clinical research as part of our QVB and expanding our communications through extensive advertising and public relations. Our brand research conducted in March 2005 gave us data from over 400 end-users of both QuickVue® and non-QuickVue® brands and indicated that our brand ranked highest in perceived value and overall performance among influenza and Group A Strep brands and second related to pregnancy brands. Our extensive VOC survey included primary research in both the domestic and international markets to better focus our product marketing and distribution partner plans. We also anticipate performing analytical studies for other products, as we did at the University of Rochester in May 2005 for our QuickVue Influenza A + B test. In this study, the QuickVue Influenza A + B test outperformed three key competitors 95% of the time. Also our extensive public relations and advertising campaign, as evidenced by our post-season influenza research that indicated why physicians adopted our influenza test, helped encourage adoption and educate consumers and professionals.

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 64%, 56% and 58% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively. Even though our distributor mix will likely change from period to period in the future, Cardinal Healthcare Corporation (Cardinal), Sumitomo Seiyaku Biomedical Co., Ltd (Sumitomo), National Distribution Corporation (NDC), and Physician Sales and Services Corporation (PSS) have historically accounted for a significant portion of our net sales. For the years ended December 31, 2005, 2004 and 2003, Cardinal accounted for approximately 18%, 16% and 16%, respectively, of net sales; Sumitomo accounted for approximately 17%, 13% and 29%, respectively, of net sales; NDC accounted for approximately 15%, 15% and 7%, respectively, of net sales while PSS accounted for approximately 14%, 12% and 6%, respectively, of 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 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 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 and LTF 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 distributed by a third party, Packaging Plus LLC (Packaging Plus). Packaging Plus is 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, including those of Packaging Plus, have been registered with the federal FDA and the Department of Health Services of the State of California (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 could 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 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.

The use of our products in the U.S. is also regulated under CLIA. These regulations establish national quality standards for most laboratories that perform testing on human specimens to ensure reliability of test results regardless of where the test is performed. In January 2003, the Centers for Medicare & Medicaid Services (the CMS) issued a new rule under CLIA for non-waived test systems, which became effective in April 2003. It is unclear at this time what impact this new rule will have on clinical laboratories that now use our non-waived products, whether this new regulation will be considered burdensome by some users of our products, or whether there will be any adverse impact on us with implementation of these regulations.

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 the 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 pre-clinical 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 foreign manufacturers to work with an in-country caretaker to register *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 are currently involved in patent related litigation with Church & Dwight in the U.S. These matters are discussed in detail in Risk Factors, below, in Item 3, entitled Legal Proceedings, and in Note 6. Commitments and Contingencies in the Notes to Consolidated Financial Statements included in this Annual Report.

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. As of December 31, 2005, our competition in our largest product areas is as follows: Beckman Coulter Primary Care Diagnostics (Beckman) and Fisher Scientific Corporation (Fisher), for pregnancy tests; Genzyme Diagnostics Corporation (Genzyme), Wampole Laboratories LLC (Wampole), Thermo Biostar, Inc. (Thermo) and Becton Dickinson and Company (Becton), for Group A Strep tests; and Becton, Binax, Inc. (Binax), Remel, Inc. (Remel), Thermo and Wampole, for influenza tests. 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, 2005, we had 255 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, 2005 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, 52, became our President and Chief Executive Officer on August 20, 2004. She has more than 25 years experience in healthcare. Prior to joining Quidel, 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 of 1996 to January of 2000. Ms. Mason s additional healthcare experience includes her tenure with Bayer AG/AGFA from October of 1989 to July of 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., MiraMedica, Inc., and currently serves as a member of the Board of Directors of AdvaMed.

Paul E. Landers, 58, has been Senior Vice President, Finance and Administration, and Chief Financial Officer since March 2003. 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.

Mark E. Paiz, 44, 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.

Dr. Thomas J. Foley, 66, 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., 37, joined us as General Counsel and Vice President on July 18, 2005. 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.

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, 2005, net sales increased 17% to $88.7 million from $76.1 million for the year ended December 31, 2004. 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, the length, and severity of the cold and flu seasons;

- recent 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 H5N1 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 or 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;

- 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.

We are involved in pending, and may become involved in future, intellectual property infringement disputes, which are costly and could limit or eliminate our ability to use certain of our core technologies in the future and sell our products.

As previously disclosed, beginning in February 2004, a number of legal proceedings were initiated by us and/or Inverness Medical Innovations Inc. (IMA) and/or their 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, Applied Biotech, Inc. (Applied), Armkel LLC (now Church & Dwight), Wampole Laboratories LLC (Wampole), Inverness Medical Switzerland GmbH (IMA Switzerland) and Unipath Diagnostics GmbH (Unipath) were parties also involved in the legal proceeding.

In April 2005, we entered into an agreement with IMA settling all domestic and international actions involving us, IMA, and IMA s affiliates (Applied, Wampole, IMA Switzerland and Unipath). Under the terms of the settlement agreement, we and IMA agreed to cross-license, and to cause their affiliates to cross-license, the parties respective lateral flow patent portfolios and to dismiss, and to cause their affiliates to dismiss, the parties respective cases. We agreed to make a net payment to IMA of $17.0 million and to pay net royalties of 8.5% on future sales of our current lateral flow products and future lateral flow products that utilize or incorporate any inventions claimed in the valid and enforceable claims of IMA lateral flow patents. The payment of the $17.0 million was made in April 2005.

Our declaratory relief action against Church & Dwight has not been settled, nor has Church & Dwight s claim for patent infringement, which seeks damages against us for over-the-counter sales and preliminary and permanent injunctions in the over-the-counter market.

There is not a specific amount or range sought in damages in the Church & Dwight lawsuit discussed above. Given the early stage of the action, we cannot predict the ultimate outcome of this matter at this time. As a result, in accordance with SFAS No. 5 Accounting for Contingencies , we have disclosed the existence of this lawsuit; however, no accrual for potential losses, if any, has been recorded.

Additionally, one other industry participant has sent us correspondence requesting that we obtain a license to patents for which it has alleged enforcement rights. We are continuing to assess the relevant intellectual property in light of our own business strategies and the costs and risks associated with defending our position. In this regard, we continue to evaluate the license request, which may result in our payment of royalties under royalty-bearing licenses in a future period. Such royalty payments could result in a material increase in our product costs and have a material adverse effect on our profits. Further, no assurance can be given that we would be able to obtain any license to third-party intellectual property under commercially reasonable terms, if at all.

We are also involved in other 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 us. We also maintain insurance, including coverage for product liability claims, in amounts which management believes appropriate given the nature of our business.

As a more general matter, our involvement in litigation, as may arise from time to time, to determine rights in proprietary technology could adversely affect our net sales and business because:

- the pendency of any litigation may of itself cause our distributors 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 the third-party patent claims valid and infringed by our products;
- 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;
- failure to obtain a necessary license upon an adverse outcome could prevent us from selling our current products or other products we may develop; and
- a court could award a preliminary and/or permanent injunction which would prevent us from selling our current or future products.

To remain competitive, we must continue to develop or obtain proprietary technology rights; otherwise, other companies may increase their market share by selling 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 introduce new technologies and products and develop new markets. Our failure to successfully introduce new technologies, new 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, including, without limitation, our strategic efforts relating to: (i) our LTF technology platform and migration of products to that platform and (ii) identifying and commercializing new markers and products in oncology and bone health. The development of new markets also requires a substantial investment of resources, such as new employees, offices and manufacturing facilities. Accordingly, we are likely to incur increased operating expenses as a result of our increased investment in sales and marketing activities, manufacturing scale-up and new product development associated with our efforts to:

- provide clinicians with validated, value-based proof which encompasses the clinical efficacy and economic efficiency of our rapid POC tests for the professional market;
- strengthen market and brand leadership in infectious disease and reproductive health;
- drive growth by establishing dedicated distributor partnerships;
- drive profit through further refinement of industry leading manufacturing efficiencies;
- identify and commercialize new markers, products and collaborations in oncology and bone health through our SPG;

- complete the full-scale manufacturability feasibility study for our LTF immunoassay and continue parallel pathways for development and acquisition of other qualitative and quantitative technology platforms;

- develop and maintain key relationships with third parties and cooperative collaborations; and

- aggressively 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 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 distributor relationships with approximately 80 distributors, 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 64%, 56% and 58% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively. 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. In addition, because we do not have experience in direct distribution and marketing, our direct distribution efforts may not be successful. 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.

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. As of December 31, 2005, our estimated U.S. professional market share for our key POC products was 66% in influenza, 50% for pregnancy and 46% for Group A Strep tests. There are, however, a large number of multinational and regional competitors making investments in competing technologies and products, including several large pharmaceutical and diversified healthcare companies. These competitors include Beckman, Fisher, Wampole, Becton, Genzyme, IMA, Binax, Remel, and Thermo. 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. 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 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. 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, 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 payors. Our net sales could also be adversely affected by changes or trends in reimbursement policies of these governmental or private healthcare payors. In the U.S., healthcare providers such as hospitals and physicians who purchase diagnostic products generally rely on third-party payors, 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 payors may reduce the demand for our products or adversely impact our ability to sell our products on a profitable basis.

Unexpected increases in 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, 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 San Diego and Santa Clara 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 26%, 29% and 41% of our net sales for the years ended December 31, 2005, 2004 and 2003, 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 13% and 14% decrease in value of the Euro and Yen, respectively, against the U.S. dollar for the year ended December 31, 2005;

- 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 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.

Evolving regulation of corporate governance and public disclosure may result in additional expenses and continuing uncertainty.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, recent SEC regulations and Nasdaq Stock Market Inc. rules and regulations, are creating significant expenses and uncertainty for companies such as ours. These recent or

changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management and Board of Directors time and attention from revenue-generating activities and operational oversight to compliance activities. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, regulatory authorities or others may initiate legal proceedings against us and we may be adversely impacted.

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 public companies 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 recent requirements, including internal control reforms, if any, to comply with Section 404 s requirements, and how independent registered public accounting firms are applying these recent 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.

Future changes in financial accounting standards or practices or existing taxation rules or practices may affect our reported results of operations.

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practices have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, changes have been approved by the Financial Accounting Standards Board, or FASB, that require that we record compensation expense in our statements of operations for equity compensation instruments, including employee and director stock options, using the fair value method. Although there will be no change in our total cash flows, our reported financial results beginning in the first quarter of 2006 will be negatively and materially impacted by this accounting change. Other potential changes in existing taxation rules related to stock options and other forms of equity compensation could also have a significant negative effect on our reported results.

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, 2005, the closing price of our common stock, as reported on the Nasdaq National Market System, has ranged from a low of $3.55 to a high of $15.51. 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;

- recent 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 H5N1 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 or 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 National Market System 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, 2005:

- approximately 33.8 million shares of our common stock had been issued in registered offerings and 33.2 million are freely tradable in the public markets, and 0.6 million relate to restricted shares;

- approximately 2.5 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 $5.09, for stock options; and

- we had in effect registration statements under the Securities Act of 1933 registering approximately 4.3 million shares of common stock reserved under our equity incentive plan. In addition, there were 213,077 shares reserved under our employee stock purchase plan.

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. 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

As previously disclosed, beginning in February 2004, a number of legal proceedings were initiated by us and/or IMA and/or their 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, Applied, Church & Dwight, Wampole, IMA Switzerland and Unipath were parties also involved in the legal proceedings.

In April 2005, we entered into an agreement with IMA settling all domestic and international actions involving us, IMA, and IMA s affiliates (Applied, Wampole, IMA Switzerland and Unipath). Under the terms of the settlement agreement, we and IMA agreed to cross-license, and to cause their affiliates to cross-license, the parties respective lateral flow patent portfolios and to dismiss, and to cause their affiliates to dismiss, the parties respective cases. We agreed to make a net payment to IMA of $17.0 million and to pay net royalties of 8.5% on future sales of our current lateral flow products and future lateral flow products that utilize or incorporate any inventions claimed in the valid and enforceable claims of IMA lateral flow patents. The payment of the $17.0 million was made in April 2005.

Our declaratory relief action against Church & Dwight has not been settled, nor has Church & Dwight s claim for patent infringement, which seeks damages against us for over-the-counter sales and preliminary and permanent injunctions in the over-the-counter market.

There is not a specific amount or range sought in damages in the Church & Dwight lawsuit discussed above. Given the early stage of the action, we cannot predict the ultimate outcome of this matter at this time. As a result, in accordance with SFAS No. 5 Accounting for Contingencies , we have disclosed the existence of this lawsuit; however, no accrual for potential losses, if any, has been recorded.

Additionally, one other industry participant has sent us correspondence requesting that we obtain a license to patents for which it has alleged enforcement rights. We are continuing to assess the relevant intellectual property in light of our own business strategies and the costs and risks associated with defending our position. In this regard, we continue to evaluate the license request, which may result in our payment of royalties under royalty-bearing licenses in a future period. Such royalty payments could result in a material increase in our product costs and have a material adverse effect on our profits. Further, no assurance can be given that we would be able to obtain any license to third-party intellectual property under commercially reasonable terms, if at all.

We are also involved in other 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 us. We also maintain insurance, including coverage for product liability claims, in amounts which management believes appropriate given the nature of our business.

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 2005.

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 National Market System under the symbol QDEL. The following table sets forth the range of high and low closing prices for our common stock for the periods indicated.

Quarter Ended	Low	High
December 31, 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
December 31, 2004	$ 4.37	$ 6.95
September 30, 2004	3.00	5.95
June 30, 2004	5.05	8.96
March 31, 2004	6.32	13.98

No cash dividends were declared for our common stock during the fiscal years ended in 2005 or 2004, and we do not anticipate paying any dividends in the foreseeable future. There were no repurchases of equity securities under our share repurchase program during the fourth quarter of 2005. As of March 1, 2006, we had approximately 661 common stockholders of record.

The table below sets forth information regarding repurchases of our common stock by us during the three months ended December 31, 2005.

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced program	Approximate dollar value of shares that may yet be purchased under the program(1)
Beginning Balance - October 1, 2005	70,500	$ 4.95	70,500	$ 24,600,000
October 1 - October 31, 2005				24,600,000
November 1 - November 30, 2005				24,600,000
December 1 - December 31, 2005(2)				24,600,000
Ending Balance - December 31, 2005	70,500	$ 4.95	70,500	$ 24,600,000

(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 June 30, 2007 unless extended by our Board of Directors.

(2) During the fourth quarter of 2005, 182 shares of common stock, at a cost of $9.99 per share, were repurchased by us in connection with payment of tax withholding obligations relating to the lapse of restrictions on certain restricted stock awards.

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,				
	2005(4)	2004	2003(3)	2002(3)	2001(1)(2)(3)
	(in thousands, except per share data)				
REVENUES					
Net sales	$ 88,731	$ 76,072	$ 90,866	$ 71,622	$ 69,344
Research contracts, license fees and royalty income	3,568	2,619	1,597	1,651	1,636
Total revenues	92,299	78,691	92,463	73,273	70,980
COSTS AND EXPENSES					
Cost of sales	37,101	35,234	40,943	35,422	34,260
Research and development	12,829	11,340	8,465	6,748	6,203
Sales and marketing	16,121	13,990	15,977	14,649	12,871
General and administrative	13,062	14,852	10,003	8,845	9,820
Patent litigation settlement	17,000				
Amortization of intangibles	1,476	1,459	1,517	1,405	3,825
Restructuring			1,966		550
Total costs and expenses	97,589	76,875	78,871	67,069	67,529
Operating earnings (loss)	(5,290)	1,816	13,592	6,204	3,451
OTHER INCOME (EXPENSE)					
Interest income	722	398	154	13	57
Interest expense	(808)	(886)	(980)	(960)	(1,314)
Other income	49	256	253	317	1,821
Total other income (expense)	(37)	(232)	(573)	(630)	564
Earnings (loss) from continuing operations before (benefit) provision for income taxes	(5,327)	1,584	13,019	5,574	4,015
(Benefit) provision for income taxes	3,000		(8,315)	2,182	3,330
Earnings (loss) from continuing operations	(8,327)	1,584	21,334	3,392	685
Loss from discontinued operations, net of taxes	(932)	(7,871)	(1,683)	(2,101)	(493)
Net earnings (loss)	$ (9,259)	$ (6,287)	$ 19,651	$ 1,291	$ 192
Basic earnings (loss) per share:					
Continuing operations	$ (0.26)	$ 0.05	$ 0.73	$ 0.12	$ 0.02
Discontinued operations	(0.03)	(0.25)	(0.06)	(0.07)	(0.02)
Net earnings (loss)	(0.28)	(0.20)	0.67	0.04	0.01
Diluted earnings (loss) per share:					
Continuing operations	$ (0.26)	$ 0.05	$ 0.70	$ 0.11	$ 0.02
Discontinued operations	(0.03)	(0.25)	(0.06)	(0.07)	(0.02)
Net earnings (loss)	(0.28)	(0.20)	0.65	0.04	0.01
Shares used in basic per share calculation	32,525	31,487	29,177	28,824	28,287
Shares used in diluted per share calculation	32,525	32,386	30,374	29,629	29,282

Balance Sheet Data

	December 31				
	2005(4)	2004	2003	2002	2001
	(in thousands)				
Cash and cash equivalents	$ 34,930	$ 36,322	$ 25,627	$ 2,910	$ 3,396
Working capital	$ 43,984	$ 49,769	$ 49,529	$ 24,002	$ 17,791
Total assets	$ 113,848	$ 112,691	$ 117,249	$ 82,593	$ 82,393
Long-term obligations	$ 9,986	$ 10,780	$ 11,258	$ 11,438	$ 11,316
Stockholders equity	$ 87,243	$ 90,185	$ 89,780	$ 62,757	$ 59,748
Common shares outstanding	33,778	31,848	30,406	28,889	28,682

(1) The year ended December 31, 2001 includes $2.5 million of amortization of goodwill that was not recorded during 2002, 2003 and 2004, pursuant to our adoption of SFAS No. 142, Goodwill and Other Intangible Assets (SFAS No. 142). The impact on fully diluted earnings per share for the year ended December 31, 2001 was $0.09.

(2) We have included $1.6 million of insurance proceeds in other income for the year ended December 31, 2001.

(3) These periods have been restated for the impact of discontinued operations, which occurred during the fourth quarter of 2004. For additional information regarding our discontinued operations, see Note 9 of the Notes to Consolidated Financial Statements.

(4) During the second quarter of 2005, we entered into an agreement to settle certain patent litigation as discussed in Part I, Item 3, Legal Proceedings and elsewhere in this Annual Report. 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.

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

Future Uncertainties

The following discussion 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 enjoy a leadership position in the development, manufacturing and marketing of rapid diagnostic solutions at the 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 product sales to professionals 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 significant portion of our net sales from three product lines. We derived approximately 82%, 77% and 79% of our net sales from sales of our influenza, Group A Strep and pregnancy tests, for the years ended December 31, 2005, 2004 and 2003, respectively. In the U.S., we lead the professional market in these three product categories with an estimated 66%, 50% and 46% market share in influenza, pregnancy and Group A Strep products, respectively, as of December 31, 2005. Additionally, 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 64%, 56% and 58% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively.

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 products managed by our SPG have a significant market share and the SPG revenues, earnings and assets are less than 10% of our overall operations.

Our product sales increased to $88.7 million from $76.1 million for the years ended December 31, 2005 and 2004, respectively. We believe the increase in sales of our core products was largely due to the development and commitment to our Quidel Value Build (QVB). 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 need 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.

During 2005, we invested in several key areas: baselining our brand equity, more in depth analysis related to voice of the customer (VOC), expanding clinical research as part of our QVB and expanding our communications through extensive advertising and public relations. Our brand research conducted in March 2005 gave us data from over 400 end-users of both QuickVue® and non-QuickVue® brands and indicated that our brand ranked highest in perceived value and overall performance among influenza and Group A Strep brands and second related to pregnancy brands. Our extensive VOC survey included primary research in both the domestic and international markets to better focus our product marketing and distribution partner plans. We also anticipate performing analytical studies for other products, as we did at the University of Rochester in May 2005 for our QuickVue Influenza A + B test. In this study, the QuickVue Influenza A + B test outperformed three key competitors 95% of the time. Also our extensive public relations and advertising campaign, as evidenced by our post-season influenza research that indicated why physicians adopted our influenza test, helped encourage adoption and educate consumers and professionals.

As of December 31, 2005, we had approximately $34.9 million in cash and cash equivalents, and had $30.0 million of availability under our credit facility. Also, during the second quarter of 2005, we settled our ongoing patent litigation with IMA. 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.

We believe that the trend among healthcare providers to adopt POC testing is increasing, 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 payors 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;
- strengthen market and brand leadership in infectious disease and reproductive health;
- drive growth by establishing dedicated distributor partnerships;
- drive profit through further refinement of industry leading manufacturing efficiencies;
- identify and commercialize new markers, products and collaborations in oncology and bone health through our SPG;
- complete the full-scale manufacturability feasibility study for our LTF immunoassay and continue parallel pathways for development and acquisition of other qualitative and quantitative technology platforms;
- develop and maintain key relationships with third parties and cooperative collaborations; and
- aggressively pursue licensing, acquisition and partnership opportunities.

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 specialized 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 60%, 55% and 60% of net sales for the years ended December 31, 2005, 2004 and 2003, respectively, are subject to, and significantly affected by, the seasonal demands of the cold and flu seasons.

In September 2005, we entered into an Asset Purchase Agreement with Alfa, in which we acquired an iFOB test product and obtained a license for certain intellectual property relating to the iFOB test product for $5.0 million. The iFOB test is FDA-cleared and CLIA-waived and is being marketed to healthcare professionals as the QuickVue iFOB test.

In November 2005, we entered into a net cross-license agreement with Dade whereby we paid Dade $1.5 million and both parties agreed to cross-license their respective patent portfolios solely directed to immunochromatographic lateral flow test strip devices with respect to current products and based on the terms of the cross-license agreement.

As part of our QVB commitment, we announced the results of clinical and analytical studies conducted to further validate the performance of our QuickVue Influenza A+B test. The clinical study was completed in Australia during that continent s flu season from July through September 2005 and showed 96% sensitivity (true positive identification) and 97% specificity (true negative identification) in detecting type A influenza when final results were validated using the RT PCR method for laboratory accuracy. The analytical study at the University of Rochester Medical Center demonstrated that our test had the highest sensitivity, 95% of the time, was the easiest to use and provided the most rapid time to result compared with certain competing rapid tests.

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.

In the accompanying financial statements, our urinalysis and ultrasonometer businesses are reported as discontinued operations under SFAS No. 144. We discontinued all operations of our ultrasonometer business during the fourth quarter of 2004, and 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.

Outlook

For fiscal year 2006, we anticipate overall revenue growth in our core product lines, as well as revenue from new product launches, primarily our recently launched iFOB test. We believe gross margins will continue in the current range as we are positively affected by increased sales volumes, a more favorable product and geographical mix and increases in average selling prices while being offset by increased investment in operational efficiencies and the annualized impact of a change in our royalty component with IMA. We expect continued growth in revenues and market share in many of our core product lines through our focused efforts on QVB, as well as an expanded portfolio of product offerings. We anticipate continued investment spending in marketing and clinical trials as we launch new products and further validate the clinical efficacy and economic efficiency of our existing products. 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 acquired and new technologies.

However, our sales expectations for future periods are based on estimated end-user demand for our products, and sales to our distribution partners would fall short of expectations if distributor inventories increase because of less than estimated end-user consumption. You should also refer to Item 1A, Risk Factors section included in 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,					
	2005		**2004**		**2003**	
REVENUES						
Net sales	96.1	%	96.7	%	98.3	%
Research contracts, licenses and royalties	3.9		3.3		1.7	
Total revenues	100.0		100.0		100.0	
COSTS AND EXPENSES						
Cost of sales	40.2		44.8		44.3	
Research and development	13.9		14.4		9.2	
Sales and marketing	17.5		17.8		17.3	
General and administrative	14.1		18.8		10.8	
Patent litigation settlement	18.4					
Amortization of intangibles	1.6		1.9		1.6	
Restructuring	0.0		0.0		2.1	
Total costs and expenses	105.7		97.7		85.3	
Operating earnings (loss)	(5.7	)	2.3		14.7	
OTHER INCOME (EXPENSE)						
Interest Income	0.8		0.5		0.2	
Interest expense	(0.9	)	(1.1	)	(1.1	)
Other income	0.1		0.3		0.3	
Total other income (expense)	(0.0	)	(0.3	)	(0.6	)
Earnings (loss) from continuing operations before (benefit) provision for income taxes	(5.8	)	2.0		14.1	
(Benefit) provision for income taxes	3.3				(9.0	)
Earnings (loss) from continuing operations	(9.0	)	2.0		23.1	
Loss from discontinued operations, net of taxes	(1.0	)	(10.0	)	(1.8	)
Net earnings (loss)	(10.0	)%	(8.0	)%	21.3	%

Net Sales

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%, 77% and 79% of our net sales for the years ended December 31, 2005, 2004 and 2003.

The increase in sales of our influenza products 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 our Japanese market for the year ended December 31, 2005. 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 existing 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. As of December 31, 2005, our influenza products have an estimated 15% market share in Japan and 66% market share in the U.S., where we are the market leader.

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. As of December 31, 2005, our U.S. professional market share is an estimated 50% for our pregnancy products, and we are the market leader.

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. See Part I, Item 3, Legal Proceedings for a discussion of the settlement reached in connection with this litigation. Additionally, during the quarter ended March 31, 2005, we implemented a price increase in our Group A Strep products. As of December 31, 2005, we maintain a market leadership position of an estimated 46% for our Group A Strep products in the U.S.

Net sales decreased 16% to $76.1 million for the year ended December 31, 2004 from $90.9 million for the year ended December 31, 2003. The decrease was largely driven by decreases in sales of our influenza, Group A Strep and pregnancy products of $11.8 million, $0.9 million and $0.5 million, respectively. These three product lines collectively accounted for 77% of our net sales during 2004. The decrease in sales of our influenza products was primarily due to a delay in shipments of our new influenza A+B test in Japan, partially offset by increased sales of our influenza products in the U.S. The delay in Japan was primarily due to a weak flu season, which ended abruptly in the early part of the first quarter of 2004. This resulted in significant quantities of our influenza A/B test remaining in our Japanese distributor s distribution channel, which also prevented us from shipping our new influenza A+B product during the late third quarter and early fourth quarter of 2004, as originally anticipated. As a result, net sales to our Japanese distributor decreased as a percentage of our total net sales to 13% in 2004 from 29% in 2003. We began shipping our new influenza A+B product late in the fourth quarter of 2004. The decrease in sales of our pregnancy products was primarily related to decreased revenues in our German market, partially offset by a slight increase within our U.S. market. In Germany, as we transitioned to a distribution model during late 2003 and 2004, our average selling price declined as expected, further impacted by a decline in unit volume, primarily due to the transition to our new distributor. We believe the decrease in our Group A Strep product sales was primarily due to a drop off in orders for Group A Strep test products as a result of U.S. distributor confusion or concern created by the then ongoing intellectual property litigation initiated during the first part of 2004.

Research Contracts, License Fees and Royalty Income

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 a Fortune 500 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 a patented technology utilized by a third

party. The agreement covering the third party royalty payments extends through November 2009, the expiration date of the patent.

Research contracts, license fees and royalty income increased to $2.6 million for the year ended December 31, 2004 from $1.6 million for the year ended December 31, 2003. This increase was primarily related to $1.0 million of research contract revenue that we earned in connection with achieving certain milestones under the joint development agreement as described above. Additionally, we had $1.6 million of upfront fees recorded as deferred revenue in the accompanying balance sheets for both periods ended December 31, 2004 and 2003. The remaining balance of $1.6 million within research contracts, license fees and royalty income for 2004 relates to royalty payments received on a patented technology of ours utilized by a third party.

Cost of Sales and Gross Profit from Net Sales

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 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. This increase in gross profit was partially offset by an 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 as discussed below and elsewhere in this Annual Report.

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. Additionally, during the first quarter of 2005, we fulfilled the terms of an agreement with another party related to the development of our influenza product. As a result, we are no longer required to pay to this party a 6.00% royalty on sales of our influenza products. Our influenza products sales accounted for 38%, 34% and 41% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively.

In connection with the patent litigation settlement entered into during the second quarter of 2005 with IMA, we are required, beginning May 2005, to pay an 8.5% royalty on net sales of our current influenza, Group A Strep, pregnancy, H.pylori, mononucleosis, chlamydia and veterinary products. These product sales collectively accounted for 91%, 88% and 90% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively, and will continue to represent a majority of our revenues for the foreseeable future.

Gross profit from net sales decreased to $40.8 million for the year ended December 31, 2004 from $49.9 million for the year ended December 31, 2003. Gross profit from net sales as a percentage of net sales decreased to 54% for the year ended December 31, 2004 from 55% for the year ended December 31, 2003. The decrease was primarily due to lower sales volume and a less favorable mix related to our influenza, Group A Strep and pregnancy products in 2004, partially offset by cost savings in 2004 relating to our restructuring activities which occurred during 2003. During the fourth quarter of 2004, a patent expired relating to one of the licensing agreements we have with a third party. This licensing agreement required us to pay royalties ranging from 5.00% to 5.25% on our influenza, Group A Strep, pregnancy, H.pylori, mononucleosis and veterinary products. We continue to pay a 5.25% royalty to this third party related to certain international sales of our influenza, Group A Strep, pregnancy, H.pylori, mononucleosis and veterinary products. As a result, our royalty expense was favorably impacted by $0.9 million for the year ended December 31, 2004. Royalty expense related to this licensing agreement was $1.5 million and $3.1 million for the years ended December 31, 2004 and 2003, respectively.

Research and Development Expense

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 decreased to 14% of net sales for the year ended December 31, 2005, as compared to 15% of net sales for the year ended December 31, 2004, largely due to increased net sales volume in 2005. The absolute dollar increase is primarily attributable to increased personnel related costs of $0.6 million, outside services of $0.4 million, laboratory supplies of $0.2 million and facility utilization of $0.9 million related to our LTF technology platform, as well as increases of $0.2 million related to clinical trials in support of our QVB. The increases were partially offset by a decrease in patent related expenses of $0.8 million during 2005.

Research and development expense increased to $11.3 million for the year ended December 31, 2004 from $8.5 million for the year ended December 31, 2003. Research and development expense as a percentage of net sales increased to 15% of net sales for the year ended December 31, 2004, as compared to 9% of net sales for the year ended December 31, 2003, largely due to lower net sales volume in 2004. The absolute dollar increase is primarily attributable to increased personnel related costs of $1.5 million and laboratory supplies of $0.4 million related to the development of products on our LTF technology platform, customer sponsored research expenses of $0.6 million related to our collaborative development efforts with a Fortune 500 company, and increased patent costs of $0.2 million associated with patent development and protection.

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 $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 of $1.3 million, as well as a $0.8 million increase in sales and marketing related programs and events to support our focused efforts on our QVB program and reinforcing relationships with key distributors.

Sales and marketing expense decreased to $14.0 million for the year ended December 31, 2004 from $16.0 million for the year ended December 31, 2003. Sales and marketing expense as a percentage of net sales remained constant at 18% for the years ended December 31, 2004 and 2003. The absolute dollar decrease relates primarily to cost savings of $2.0 million in 2004 related to our restructuring activities undertaken during 2003, including the closure of our sales and support offices in Germany and Italy, and to a lesser extent certain variable costs tied directly to our lower net sales, including freight out of $0.4 million, and commissions and customer promotions of $0.8 million. These cost savings were partially offset by increased costs of $1.0 million associated with market research, promotion, public relations and advertising fees related to our influenza, Group A Strep and pregnancy products.

General and Administrative Expense

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 compensation expense related to officers and directors restricted shares and $1.0 million related to the CEO changes in 2004.

General and administrative expense increased to $14.9 million for the year ended December 31, 2004 from $10.0 million for the year ended December 31, 2003. General and administrative expense as a percentage of net sales increased to 20% for the year ended December 31, 2004 from 11% for the year ended December 31, 2003. The absolute dollar increase in 2004 was primarily due to legal fees associated with our intellectual property litigation of $5.0 million, higher professional fees related to compliance with the Sarbanes-Oxley Act of 2002, as well as costs incurred in connection with the hiring of a new Chief Executive Officer and departure of our former Chief Executive Officer of $1.0 million, partially offset by higher professional fees during 2003 related to the re-audit of our fiscal 2001 financial statements of $0.4 million and personnel related costs of approximately $0.5 million.

Patent Litigation Settlement

During the second quarter of 2005, we entered into an agreement to settle certain patent litigation as discussed in Part I, Item 3, Legal Proceedings and elsewhere in this Annual Report. 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. For additional information regarding our patent litigation settlement, see Note 6 of Notes to Consolidated Financial Statements included in this Annual Report.

Restructuring

In April 2003, we announced and implemented a restructuring plan (the Restructuring Plan). The Restructuring Plan was primarily driven by manufacturing automation in our San Diego facility, completion of certain research and development projects, implementation of our BaaN enterprise resource planning system in our Santa Clara facility, and the transition of our foreign sales and support offices to independent distributors. As of December 31, 2004, the entire $2.0 million of the restructuring charge had been paid.

Amortization of Intangibles

On January 1, 2002, we adopted SFAS No. 141, Business Combinations, (SFAS No. 141) and SFAS No. 142, which eliminated the amortization 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, 2005 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 three to 12 years, include purchased technology, license agreements, patents, trademarks and a favorable lease.

Amortization expense was $1.5 million for each of the years ended December 31, 2005, 2004 and 2003.

Other Income (Expense)

Interest expense was $0.8 million, $0.9 million and $1.0 million for the years ended December 31, 2005, 2004 and 2003, respectively, and relates primarily to interest paid on obligations under capital leases, which are primarily related to our San Diego facility. Interest income was $0.7 million, $0.4 million and $0.2 million for the years ended December 31, 2005, 2004 and 2003, respectively, and relates to interest earned on our cash and cash equivalents balance.

Income Taxes

Income tax expense was $3.0 million for the year ended December 31, 2005 as compared to no tax expense recorded for the year ended December 31, 2004. 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.

We recorded a tax benefit of $8.3 million for the year ended December 31, 2003, which was primarily due to a decrease in the deferred tax valuation allowance during the fourth quarter ended December 31, 2003 to recognize deferred tax assets at amounts considered by management, more likely than not, to be realized, and to a lesser extent, foreign operations for both periods. At that time, based on the then recent history of profitability and the forecasts for future periods, management determined it was more likely than not that net operating loss carryforwards and other temporary differences would be realized.

Loss from discontinued operations, net of taxes

In the accompanying financial statement, our urinalysis and ultrasonometer businesses are reported as discontinued operations under of SFAS 144. 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. The loss from discontinued operations, net of taxes, was $0.9 million, $7.9 million and $1.7 million for the years ended December 31, 2005, 2004 and 2003, respectively.

Liquidity and Capital Resources

As of December 31, 2005, our principal source of liquidity consisted of $34.9 million in cash and cash equivalents. Our working capital as of December 31, 2005 was $44.0 million.

Our earnings from continuing operations provided cash of $1.4 million during 2005. We had losses from continuing operations of $8.3 million, including $5.5 million of depreciation and amortization of intangible assets. Other changes in operating assets and liabilities included an increase in accounts receivable and inventory of $0.5 million and $0.9 million, respectively, due to our increase in net sales, increase in accounts payable of $0.8 million and accrued royalties of $1.2 million, both as a result of increased net sales, a decrease in deferred revenue of $1.6 million related to the termination of a joint development agreement we had with a third party, and the related upfront fees being recognized as revenue and an increase in other current liabilities of $1.2 million primarily due to liabilities associated with the acquisition of our iFOB test as well as employee bonuses. Our earnings from continuing operations provided cash of $12.0 million during 2004. We had earnings from continuing operations of $1.6 million, including $5.5 million of depreciation and amortization of intangible assets. Other changes in operating assets and liabilities included a decrease in accounts receivable of $8.8 million due to our decrease in net sales and earlier collections of outstanding receivables, an increase in inventory of $0.3 million due to lower than expected net sales, decreases in accounts payable of $1.0 million and accrued royalties of $1.2 million, both as a result of decreased net sales, and a decrease in other current

liabilities of $2.6 million, which included lower volume discounts of $1.7 million as a result of lower net sales and $1.0 million of bonuses earned during 2003.

Our investing activities used $7.7 million and $5.3 million of cash during 2005 and 2004, respectively. For 2005, this included $3.2 million for the acquisition of manufacturing equipment for our LTF products and other assets related to information technology, as well as $4.3 million related to assets and licenses acquired primarily for our iFOB test. For 2004, this included $4.6 million for the acquisition of manufacturing equipment for our LTF products and other assets related to information technology, as well as $0.9 million for certain intellectual property.

We currently have $2.7 million of firm purchase commitments with respect to the acquisition of the iFOB test. These commitments relate to inventory component purchases from Alfa. We are planning $5.1 million in capital expenditures for fiscal 2006. The primary purpose for our capital expenditures is to acquire manufacturing equipment, to implement building improvements, and for information technology. We plan to fund these capital expenditures with cash flow from operations.

Our financing activities provided $5.1 million and $6.0 million of cash during the years ended December 31, 2005 and 2004, respectively. For both periods, the major source was proceeds we received from the issuance of common stock under our equity incentive plans, offset slightly by $0.5 million in both periods for payments on obligations under our capital leases related to our building in San Diego.

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, 2005, we had $30.0 million of availability under the Senior Secured Credit Facility and we were in compliance with all covenants.

We also intend to continue evaluation of acquisition and technology licensing candidates. As such, we may need to incur additional debt, or sell additional equity, to successfully complete these acquisitions. Cash requirements fluctuate as a result of numerous factors, such as the extent to which we generate cash from operations, progress in research and development projects, competition and technological developments and the time and expenditures required to obtain governmental approval of our products. Based on our current cash position and the current assessment of future operating results, we believe that our existing sources of liquidity will be adequate to meet operating needs during the next 12 months and the foreseeable future.

Off-Balance Sheet Arrangements

At December 31, 2005 and 2004, 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 agreements. 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)	$ 13,222	$ 1,406	$ 2,781	$ 2,893	$ 6,142
Operating lease obligations(2)	5.572	1,188	2,771	1,613	
Asset purchase and license agreements(3)	5,500	3,900	1,600		
Total	$ 24,294	$ 6,494	$ 7,152	$ 4,506	$ 6,142

(1) Reflects obligations on facilities and equipment under capital leases, including current maturities, in place as of December 31, 2005. 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, 2005. Future minimum lease payments are included in the table above.

(3) Reflects obligations resulting from an asset purchase and license agreements of $2.8 million, and firm purchase commitments for inventory components of $2.7 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 $7.1 million, $5.6 million and $8.7 million for the years ended December 31, 2005, 2004 and 2003, 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:

We record revenues 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. 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. 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 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 license fees in the accompanying consolidated statements of operations.

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.

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

Intangible assets 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, 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 they are 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 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 requires periodic evaluations for impairment of goodwill balances. We completed our annual evaluation for impairment of goodwill as of December 31, 2005 and determined that no impairment of goodwill existed.

During the three months ended March 31, 2005, we recorded a patent litigation settlement charge of $17.0 million and, under the terms of the settlement agreement, we are required to pay royalties on certain product sales. 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 ongoing 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. Based primarily on these changes, we recorded an income tax expense of $3.0 million during the three months ended March 31, 2005. The expense resulted from an estimated reduction in the utilization of deferred tax assets. Although realization is not assured, we have concluded that it is more likely than not that the remaining portion of deferred tax assets at December 31, 2005 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 of December 31, 2005, we recorded a valuation allowance of $4.0 million related to deferred tax assets created by the exercise and/or disposition of employee stock options in recent periods. The deferred tax asset originating from deductions for the exercise and/or disposition of stock options and the related valuation allowance have been recorded against additional paid-in capital and did not affect net earnings for the period. Any tax benefits realized from the reduction of this valuation allowance will be recorded to additional paid-in capital.

We also have recorded a valuation allowance of $7.5 million related to federal net operating losses of acquired businesses, which are available for our use. The tax benefit of these tax loss carryforwards, if and when realized, will first reduce the existing value of goodwill up to a total of $6.6 million, then, if applicable, remaining amounts will be applied first to other intangible assets, with any excess amount to be recognized as an income tax benefit.

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 our 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 upon estimates of future earnings, we determine 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, goodwill, and/or income tax expense in the period such determination is made.

Recent Accounting Pronouncements

For information on recent accounting pronouncements, which may impact our business, see Note 1 of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to the risk of currency exchange rate fluctuations, which are primarily accounted for as an adjustment to stockholders equity as they relate to our foreign subsidiaries whose functional currency is their local currency. Exchange gains and losses arising from transactions denominated in foreign currencies are recorded in operations and have historically not been material. Nonetheless, changes from reporting period to reporting period in the exchange rates between various foreign currencies and the U.S. dollar have had and will continue to have an impact on the accumulated other comprehensive income component of stockholders equity we report. However, such effect in the accounts of our foreign subsidiaries are not expected to be material in any reporting period.

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, 2005. Based on our market risk sensitive instruments outstanding at December 31, 2005 and 2004, 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, 2005, 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.

Item 8. Financial Statements and Supplementary Data

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

Part III

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

None.

Item 9A. Controls and Procedures

Evaluation of disclosure controls and procedures: We have performed an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the Exchange Act). Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of December 31, 2005 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 2005 that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Management s Report on Internal Control Over Financial Reporting: Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is a process designed to

provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2005.

Management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 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, 2005, 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, 2005, 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, 2005, 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, 2005 and 2004, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2005 and our report dated March 2, 2006 expressed an unqualified opinion thereon.

Ernst & Young LLP

San Diego, California
March 2, 2006

Item 9B. Other Information

2006 Annual Meeting of Stockholders

The Company s 2006 Annual Meeting of Stockholders will be held on Wednesday, May 17, 2006, beginning at 8:30 a.m. (local time) at L Auberge Del Mar Resort and Spa in San Diego, California.

Item 10. Directors and Executive Officers of the Registrant

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 2006 Proxy Statement, which will be filed with the SEC no later than April 30, 2006. Information with respect to executive officers is included under Item 1 on pages 15-16 of this Annual Report.

The information required by Items 405 and 406 of Regulation S-K is incorporated by reference from the information under the captions Code of Business Conduct and Ethics and Section 16(a) Beneficial Ownership Reporting Compliance, to be contained in our 2006 Proxy Statement, which will be filed with the SEC no later than April 30, 2006.

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 2006 Proxy Statement to be filed with the SEC no later than April 30, 2006.

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 2006 Proxy Statement, which will be filed with the SEC no later than April 30, 2006.

Item 13. Certain Relationships and Related Transactions

The information required by this item is incorporated by reference from the information under the captions Compensation Committee Interlocks and Insider Participation and Certain Transactions to be contained in our 2006 Proxy Statement, which will be filed with the SEC no later than April 30, 2006.

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 2006 Proxy Statement, which will be filed with the SEC no later than April 30, 2006.

Part IV

Item 15. Exhibits and Financial Statement Schedules

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

(a) (1) Financial Statements

The consolidated financial statements required by this item are submitted in a separate section beginning on page F-1 of this Annual Report and incorporated herein by reference.

Consolidated Financial Statements of Quidel Corporation

(2) Financial Statement Schedules

The following Financial Statement Schedule of Quidel Corporation for the years ended December 31, 2005, 2004 and 2003 is filed as part of this Annual Report and should be read in conjunction with the consolidated financial statements of Quidel Coproration.

Schedule II. 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 pargraph 15(b) below.

(b) Exhibits

The exhibits listed on the accompanying index to exhibits immediately following the financial statement schedules are filed as part of, and incorporated by reference into, this Annual Report on Form 10-K.

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

Not applicable.

SIGNATURES

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

QUIDEL CORPORATION

Date: March 9, 2006 By /s/ CAREN L. MASON
Caren L. Mason
President, Chief Executive Officer
(Principal Executive Officer) and Director

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

Signature	Title	Date
/s/ CAREN L. MASON Caren L. Mason	President, Chief Executive Officer (Principal Executive Officer), and Director	March 9, 2006
/s/ PAUL E. LANDERS Paul E. Landers	Senior Vice President, Finance and Administration, Chief Financial Officer and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 9, 2006
/s/ MARK A. PULIDO Mark A. Pulido	Chairman of the Board	March 9, 2006
/s/ THOMAS D. BROWN Thomas D. Brown	Director	March 9, 2006
/s/ DOUGLAS S. HARRINGTON Douglas S. Harrington	Director	March 9, 2006
/s/ RODNEY F. DAMMEYER Rodney F. Dammeyer	Director	March 9, 2006
/s/ THOMAS A. GLAZE Thomas A. Glaze	Director	March 9, 2006
/s/ MARY LAKE POLAN Mary Lake Polan	Director	March 9, 2006
/s/ FAYE WATTLETON Faye Wattleton	Director	March 9, 2006
/s/ JACK W. SCHULER Jack W. Schuler	Director	March 9, 2006

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, 2005 and 2004, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2005. 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, 2005 and 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Quidel Corporation s internal control over financial reporting as of December 31, 2005, 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 2, 2006 expressed an unqualified opinion thereon.

ERNST & YOUNG LLP

San Diego, California
March 2, 2006

QUIDEL CORPORATION
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2005	2004
	(in thousands, except per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,930	$ 36,322
Accounts receivable, net	15,819	15,274
Inventories	8,500	7,640
Prepaid expenses and other current assets	1,354	1,506
Assets held for sale		753
Total current assets	60,603	61,495
Property, plant and equipment, net	19,557	20,181
Intangible assets, net	23,964	18,527
Deferred tax assets	8,864	11,751
Other assets	860	737
Total assets	$ 113,848	$ 112,691
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,134	$ 4,292
Accrued payroll and related expenses	1,847	1,355
Accrued royalties	3,367	2,205
Deferred revenue		1,629
Current portion of obligations under capital leases	648	589
Other current liabilities	5,623	1,656
Total current liabilities	16,619	11,726
Capital leases, net of current portion	8,439	9,088
Deferred rent	1,547	1,692
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $.001 par value; 5,000 shares authorized, none issued or outstanding		
Common stock, $.001 par value; 50,000 shares authorized, 33,778 and 31,848 shares issued and outstanding at December 31, 2005 and 2004, respectively	34	32
Deferred stock compensation	(1,947)	
Additional paid-in capital	161,662	153,319
Accumulated other comprehensive earnings	1,326	1,407
Accumulated deficit	(73,832)	(64,573)
Total stockholders equity	87,243	90,185
Total liabilities and stockholders equity	$113,848	$ 112,691

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,		
	2005	2004	2003
	(in thousands, except per share data)		
REVENUES			
Net sales	$ 88,731	$ 76,072	$ 90,866
Research contracts, license fees and royalty income	3,568	2,619	1,597
Total revenues	92,299	78,691	92,463
COSTS AND EXPENSES			
Cost of sales	37,101	35,234	40,943
Research and development	12,829	11,340	8,465
Sales and marketing	16,121	13,990	15,977
General and administrative	13,062	14,852	10,003
Patent litigation settlement	17,000		
Amortization of intangibles	1,476	1,459	1,517
Restructuring			1,966
Total costs and expenses	97,589	76,875	78,871
Operating earnings (loss)	(5,290)	1,816	13,592
OTHER INCOME (EXPENSE)			
Interest income	722	398	154
Interest expense	(808)	(886)	(980)
Other income (expense)	49	256	253
Total other income (expense)	(37)	(232)	(573)
Earnings (loss) from continuing operations before (benefit) provision for income taxes	(5,327)	1,584	13,019
(Benefit) provision for income taxes	3,000		(8,315)
Earnings (loss) from continuing operations	(8,327)	1,584	21,334
Loss from discontinued operations, net of taxes	(932)	(7,871)	(1,683)
Net earnings (loss)	$ (9,259)	$ (6,287)	$ 19,651
Basic earnings (loss) per share:			
Continuing operations	$ (0.26)	$ 0.05	$ 0.73
Discontinued operations	(0.03)	(0.25)	(0.06)
Net earnings (loss)	(0.28)	(0.20)	0.67
Diluted earnings (loss) per share:			
Continuing operations	$ (0.26)	$ 0.05	$ 0.70
Discontinued operations	(0.03)	(0.25)	(0.06)
Net earnings (loss)	(0.28)	(0.20)	0.65
Shares used in basic per share calculations	32,525	31,487	29,177
Shares used in diluted per share calculations	32,525	32,386	30,374

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	Amount						
	(in thousands)							
Balance at December 31, 2002	28,889	$ 30	$ 140,358	$	$ 306	$ (77,937)	$ 62,757	$ 2,229
Issuance of common stock for cash under stock options, stock warrants and stock purchase plans	1,517	1	5,776				5,777	
Income tax benefit due to exercise/ disposition of employee stock options			702				702	
Translation adjustment					893		893	$ 893
Net earnings						19,651	19,651	19,651
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)
Common stock repurchased	(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)

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2005	2004	2003
	(in thousands)		
OPERATING ACTIVITIES			
Earnings (loss) from continuing operations	$ (8,327)	$ 1,584	$ 21,334
Adjustments to reconcile earnings from continuing operations to net cash provided by operating activities:			
Depreciation and amortization	5,466	5,544	5,628
Loss on disposal of assets	66	62	368
Compensation expense on stock awards	680		
Deferred tax asset	2,887	441	(10,566)
Changes in assets and liabilities:			
Accounts receivable	(545)	8,869	(6,044)
Inventories	(860)	(295)	1,400
Prepaid expenses and other current assets	152	99	(390)
Accounts payable	842	(941)	2,078
Accrued payroll and related expenses	492	229	42
Accrued royalties	1,162	(1,245)	1,269
Deferred rent	(145)	111	338
Deferred revenue	(1,629)	43	1,586
Other current liabilities	1,160	(2,549)	2,611
Net cash provided by continuing operations	1,401	11,952	19,654
Net cash used by discontinued operations	(179)	(2,028)	(732)
Net cash provided by operating activities	1,222	9,924	18,922
INVESTING ACTIVITIES			
Acquisition of plant and equipment	(3,157)	(4,623)	(2,494)
Acquisition of intangible assets	(4,300)	(815)	
Other assets	(211)	128	128
Net cash used for investing activities	(7,668)	(5,310)	(2,366)
FINANCING ACTIVITIES			
Proceeds from issuance of common stock, net	5,717	6,484	6,479
Payments on debt and obligations under capital leases	(590)	(519)	(454)
Payments on line of credit			
Net cash provided by financing activities	5,127	5,965	6,025
Effect of exchange rate changes on cash	(73)	116	136
Net increase (decrease) in cash and cash equivalents	(1,392)	10,695	22,717
Cash and cash equivalents at beginning of year	36,322	25,627	2,910
Cash and cash equivalents at end of year	$ 34,930	$ 36,322	$ 25,627
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid for interest	$ 808	$ 856	$ 881
Cash paid for income taxes	$	$ 310	$ 998
NON-CASH INVESTING ACTIVITIES			
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

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, 2005 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 $1.1 million and $1.3 million at December 31, 2005 and 2004, 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 and $0.6 million for December 31, 2005 and 2004, respectively (in thousands):

	December 31,	
	2005	2004
Raw materials	$ 3,414	$ 2,641
Work-in-process	2,682	2,501
Finished goods	2,404	2,498
	$ 8,500	$ 7,640

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. 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):

	December 31,	
	2005	2004
Equipment, furniture and fixtures	$ 33,836	$ 35,564
Building and improvements	17,717	17,309
Land	1,080	1,080
	52,633	53,953
Less: Accumulated depreciation and amortization	(33,076)	(33,772)
	$ 19,557	$ 20,181

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. The excess of cost over fair value of the net tangible assets purchased (goodwill) arose from the Company s acquisition of its wholly owned subsidiaries Litmus Concepts, Inc. (Litmus) and Metra Biosystems, Inc. (Metra) and the purchase of technology from Litmus. The technology purchased from Litmus is being amortized over seven years. Patent filing costs are capitalized and amortized upon the issuance of the related patent. License and favorable lease arrangements are being amortized over the terms of the related agreements.

Intangible assets consisted of the following (in thousands):

		December 31	
	Life	2005	2004
Goodwill	N/A	$ 16,520	$ 16,520
Purchased technology	7 years	6,100	6,100
License agreements	1 to 8 years	10,400	3,300
Patent and trademark costs	10 to 12 years	3,623	3,623
Favorable lease and other	3 to 9 years	1,700	1,700
		38,343	31,243
Less: Accumulated amortization		(14,379)	(12,716)
		$ 23,964	$ 18,527

Amortization expense was $1.5 million for each of the years ended December 31, 2005, 2004 and 2003.

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

Years Ended December 31	Amortization Expense
2006	$ 3,773
2007	2,499
2008	1,361
2009	1,345
2010	1,164
Thereafter	659
Total	$ 10,801

On January 1, 2002, the Company 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 by comparing the carrying value to the fair value of the reporting unit to which they are 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 existed. The Company completed its annual evaluation for impairment of goodwill as of December 31, 2005, and determined that no impairment of goodwill occurred. 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.

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

	December 31,	
	2005	2004
Product acquisition liabilities	$ 2,500	$
Accrued compensation	1,675	426
Volume discounts payable	285	376
Accrued professional fees	224	411
Other	939	443
	$ 5,623	$ 1,656

Revenue Recognition The Company records revenues 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. 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. 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) 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 license fees 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 $1.1 million, $0.9 million and $1.3 million for the years ended December 31, 2005, 2004 and 2003, respectively.

Advertising Costs Advertising costs are expensed as incurred. Advertising costs were $0.9 million, $1.2 million and $0.6 million for the years ended December 31, 2005, 2004 and 2003, 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.

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QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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.

Stock Compensation The Company has elected to follow Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations, in accounting for its employee stock options. Under APB No. 25, because the exercise price of the Company s employee and director stock options equals or exceeds the estimated market price of the underlying stock on the date of grant, no compensation expense has been recognized.

Adjusted pro forma information regarding net earnings is required by SFAS 123, and has been determined as if we had accounted for our employee stock-based compensation under the fair value method of that statement. The estimated weighted average fair value of options granted during the years ended December 31, 2005, 2004 and 2003 was $3.54, $4.23 and $2.85, respectively. The fair value of each option grant was estimated on the date of grant using the Black Scholes option pricing model with the following weighted average assumptions used for grants years ended as follows:

	Year ended December 31,					
	2005		2004		2003	
Risk-free interest rate	4.4	%	3.4	%	3.0	%
Expected option life	4.6		5.3		6.1	
Volatility	0.80		0.82		0.82	
Dividend Rate	0	%	0	%	0	%

The pro forma effects on net earnings (loss) for the years ended December 31, 2005, 2004 and 2003 may not be representative of the effects on reported net earnings or loss in future years. In the Company s opinion, existing stock option valuation models do not provide a reliable single measure of the fair value of employee stock options that have vesting provisions and are not transferable. In addition, option valuation models require the input of highly subjective assumptions, including expected stock price volatility. Changes in such subjective input assumptions can materially affect the fair value estimate of employee stock options.

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Had compensation cost for the Company s stock option plans been determined based on the fair value at the grant date for awards for the years ended December 31, 2005, 2004 and 2003, consistent with the provisions of SFAS No. 123, the Company s net earnings (loss) and earnings (loss) per share would have been as follows (in thousands, except per share data):

	Year ended December 31,		
	2005	2004	2003
Net earnings (loss) as reported	$ (9,259)	$ (6,287)	$ 19,651
Net earnings (loss) pro forma	(11,450)	(9,802)	15,994
Basic earnings (loss) per share as reported	(0.28)	(0.20)	0.67
Diluted earnings (loss) per share as reported	(0.28)	(0.20)	0.65
Basic earnings (loss) per share pro forma	(0.35)	(0.31)	0.55
Diluted earnings (loss) per share pro forma	(0.35)	(0.31)	0.53

Computation of Earnings (Loss) Per Share Basic earnings (loss) per share was computed by dividing net earnings (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per share reflects the potential dilution that could occur if the income were divided by the weighted average number of common shares and potentially dilutive common shares from outstanding stock options. Potentially dilutive common shares were calculated using the treasury stock method and represent incremental shares issuable upon exercise of the Company s outstanding options. 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 strike price of the stock option) are not included in diluted earnings per common share as their effect is anti-dilutive.

As we incurred losses from continuing operations during the year ended December 31, 2005, potentially dilutive shares of 1.4 million shares are not considered in the calculation of net loss per share, as their impact would be anti-dilutive. During the years ended December 31, 2004 and 2003, we had earnings from continuing operations. Accordingly, 0.7 million shares in 2004 and 0.8 million shares in 2003 were outstanding but 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.

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,		
	2005	2004	2003
Shares used in basic earnings (loss) per share (weighted average common shares outstanding)	32,525	31,487	29,177
Effect of dilutive stock options		899	1,197
Shares used in diluted earnings (loss) per share calculation	32,525	32,386	30,374

Comprehensive Earnings (loss) Comprehensive earnings (loss) includes unrealized gains and losses excluded from the Company s Consolidated Statements of Operations. The unrealized losses include

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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.

Recent Accounting Pronouncements In December 2004, FASB revised Statement No. 123 (FAS 123R), Share-Based Payment, which requires companies to expense the estimated fair value of employee and director stock options and similar awards. The accounting provisions of FAS 123R will be effective for the Company in the first fiscal quarter of 2006. Under FAS 123R, the Company will be required to measure the cost of all employee and/or director share-based payments, including grants of stock options, using a fair-value-based method. The cost of share-based payments will be recognized over the period during which an employee and director is required to provide service in exchange for the award. The pro forma disclosures previously permitted under FAS 123 no longer will be an alternative to financial statement recognition. FAS 123R permits companies to adopt its requirements using either a modified prospective method or a modified retrospective method. Under the modified prospective method, compensation cost is recognized in the financial statements beginning with the effective date, based on the requirements of FAS 123R for all share-based payments granted after that date, and based on the requirements for FAS 123 for all unvested awards granted prior to the effective date of FAS 123R. Under the modified retrospective method, the requirements are the same as under the modified prospective method, but also permit companies to restate financial statements of previous periods based on pro forma disclosures made in accordance with FAS 123. The Company has not yet determined which method or model it will use to measure the fair value of employee and director stock options under FAS 123R.

As permitted by FAS 123 and described in Note 1 above, the Company currently accounts for share-based payments to employees and directors using APB Opinion No. 25 s intrinsic value method and, as such, generally recognized no compensation cost for employee and director stock options. Accordingly, the adoption of FAS 123R s fair value method will have a significant impact on its result of operations, although it will have no impact on its overall financial position. The impact of adoption of FAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future and the assumptions for the variables which impact the computation. See Stock Compensation in Note 1 above for the pro forma net earnings and net (loss) per share amounts for the years ended December 31, 2005, 2004 and 2003 as if the Company had used a fair-value-based method similar to the methods required under FAS 123R to measure compensation expense for employee and director stock incentive awards.

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. Product Acquisition

In September 2005, the Company entered into an Asset Purchase and License Agreement (the Asset Purchase Agreement) with Alfa Scientific Designs, Inc. (Alfa), in which the Company acquired an immunochemical fecal occult blood test (the iFOB test) product and obtained a license for certain intellectual property relating to the iFOB test product for $5.0 million. Under the terms of the Asset Purchase Agreement, the Company made an initial cash payment of $2.5 million upon closing, while $1.5 million is expected to be paid during the first quarter of 2006, with the remaining $1.0 million to be paid during the third quarter of 2006 upon transfer of complete product manufacturability. In the Company s transition to complete manufacturability, Alfa will supply iFOB test product components to the Company. Under the Asset Purchase Agreement, the Company currently has firm purchase commitments of approximately $2.7 million related to product component purchases from Alfa.. As of December 31, 2005, the Company had approximately $5.0 million recorded as an intangible asset in the accompanying balance sheet, while the remaining portion to be paid of $2.5 million has been recorded in other current liabilities in the accompanying balance sheet. The intangible asset is being amortized over a period of five years.

Note 3. Line of Credit

As of December 31, 2005, 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, 2005, there were no borrowings outstanding under the Senior Secured Credit Facility and the Company was in compliance with all covenants.

Note 4. 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):

	December 31,		
	2005	2004	2003
United States	$ (5,272)	$ 279	$ 12,963
Foreign	(55)	1,305	56
	$ (5,327)	$ 1,584	$ 13,019

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4. Income Taxes (Continued)

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

	December 31,		
	2005	2004	2003
Current:			
Federal	$	$	$ 703
Foreign			100
State	113	(441)	1,448
Total current provision	$ 113	$ (441)	2,251
Deferred:			
Federal	2,368		(10,392)
State	519	441	(174)
Total deferred provision	2,887	441	(10,566)
(Benefit) provision for income taxes	$ 3,000	$	$ (8,315)

Significant components of the Company s deferred tax assets as of December 31, 2005 and 2004 are shown below (in thousands).

	December 31,	
	2005	2004
Deferred tax assets:		
Net operating loss carryforwards	$ 17,821	$ 13,163
Capitalized research and development costs	6,688	8,408
Tax credit carryforwards	2,466	1,878
Other, net	5,038	6,985
Total deferred tax assets	32,013	30,434
Valuation allowance for deferred tax assets	(22,181)	(17,104)
Deferred tax assets, net of valuation allowance	9,832	13,330
Deferred tax liabilities:		
Acquired intangibles	(985)	(1,013)
Depreciation	17	(566)
Total deferred tax liabilities	(968)	(1,579)
Net deferred tax assets	$ 8,864	$ 11,751

During the three months ended March 31, 2005, the Company recorded a patent litigation settlement charge of $17.0 million and, under the terms of the settlement agreement, the Company is required to pay royalties on certain product sales. Due to the impact of this settlement, the Company reassessed the realizability of its deferred tax assets, which have been recognized primarily based on projected earnings. As a result of revisions to the Company s estimates of projected earnings, related primarily to the effect of the $17.0 million settlement payment and ongoing royalty payments, partially offset by a projected reduction in future litigation expenses, the Company has concluded that it could not support the recognition of the same level of deferred tax assets that the Company had reported on its balance sheet as

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4. Income Taxes (Continued)

of December 31, 2004. Based primarily on these changes, the Company recorded an income tax expense of $3.0 million during the three months ended March 31, 2005.

The expense resulted from an estimated reduction in the utilization of deferred tax assets. Although realization is not assured, the Company has concluded that it is more likely than not that the remaining portion of deferred tax assets at December 31, 2005 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 of December 31, 2005, the Company recorded a valuation allowance of $4.0 million related to deferred tax assets created by the exercise and/or disposition of employee stock options in recent periods. The deferred tax asset originating from deductions for the exercise and/or disposition of stock options and the related valuation allowance have been recorded against additional paid-in capital and did not affect net earnings for the period. Any tax benefits realized from the reduction of this valuation allowance will be recorded to additional paid-in capital.

The Company also recorded a valuation allowance of $7.5 million related to federal net operating losses (NOL) of acquired businesses, which are available for its use. The tax benefit of these tax loss carryforwards, if and when realized, will first reduce the existing value of goodwill up to a total of $6.6 million, then, if applicable, remaining amounts will be applied first to other intangible assets with any excess amount recognized as an income tax benefit.

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. Conversely, if based upon estimates of future earnings, the Company 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, goodwill and/or income tax expense in the period such determination is made.

As of December 31, 2005, the Company had federal NOL carryforwards of approximately $49.6 million, including an acquired NOL of approximately $22.1 million. Approximately $2.2 million of the carryforwards are scheduled to expire during 2006, unless previously utilized. The balance of the NOL carryforwards will expire at various dates through December 31, 2025, unless previously utilized. The Company has state NOL carryforwards of $21.3 million. Approximately $0.9 million are scheduled to expire during 2006. The balance of the NOL carryforwards will expire at various dates through 2015. The Company has federal and state research credits of $0.3 million and $1.9 million, respectively. The federal credits begin to expire in 2012 and the state credits do not expire. The Company has a $0.1 million manufacturers investment tax credit which expires through 2013. The Company also has federal alternative minimum tax credit carryforwards of approximately $0.8 million that do not expire.

Pursuant to Internal Revenue Code Section 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.

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4. Income Taxes (Continued)

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

	Year ended December 31,		
	2005	2004	2003
Tax (benefit) at statutory tax rate	$ (1,811)	$ 539	$ 4,428
Federal and state research credits current year	(397)	(343)	
Federal and state research credits prior year true-up	(294)	(922)	
Foreign taxes and foreign losses not benefited	19		100
State taxes (benefit), net of federal tax (benefit)	(234)	74	662
Federal and state NOL carryforwards expired	1,372		
Change in valuation allowance	4,289	913	(13,019)
Other	56	(261)	(486)
	$ 3,000	$	$ (8,315)

Note 5. 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, 2005 and 2004.

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 (the Rights Plan), which provides for a dividend of one right (a Right) to purchase fractions of shares of the Company s Series C Junior Participating Preferred Stock for each share of the Company s common stock. Under certain conditions involving an acquisition by any person or group of 15% or more of the 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 30, 2006, unless earlier triggered, redeemed or exchanged.

Restricted Stock. For the years ended December 31, 2005 and 2004, the Company granted approximately 0.5 million and 0.1 million shares of restricted common stock to officers and directors, respectively. 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 Compensation Committee of the Board of Directors.

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 5. Stockholders Equity (Continued)

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.

As of December 31, 2005, unamortized deferred stock compensation related to restricted stock was $1.9 million and was included in stockholders equity. The Company recorded compensation expense of $0.7 million during the year ended December 31, 2005, while no material compensation expense was recorded during the year ended December 31, 2004.

Stock Options. The Company grants options to employees and non-employee directors under its 2001 Equity Incentive Plan and previously granted options under the 1998 Stock Incentive Plan and the 1996 Non-Employee Directors Stock Option Plan. The 1998 and 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 $13.09, and generally vest over four years. As of December 31, 2005, 1,277,548 shares remained available for grant under the 2001 Equity Incentive Plan.

The following table summarizes option activity in terms of thousands of shares and the weighted average exercise per share:

	Year ended December 31					
	2005		2004		2003	
	Shares	Price	Shares	Price	Shares	Price
	(in thousands, except price data)					
Outstanding at beginning of period	3,840	$ 4.84	4,479	$ 4.51	5,564	$ 4.58
Granted	291	$ 5.45	1,567	5.69	1,220	4.14
Exercised	(1,376)	$ 4.27	(1,387)	4.45	(1,467)	3.84
Cancelled	(302)	$ 6.07	(819)	5.71	(838)	5.61
Outstanding at end of period	2,453	$ 5.09	3,840	$ 4.84	4,479	$ 4.51

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 5. Stockholders Equity (Continued)

The following table summarizes information as of December 31, 2005 concerning options outstanding:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price of Options Exercisable
$2.25 - $3.43	248,003	6.20	$ 3.17	171,233	$ 3.17
$3.46 - $3.46	450,000	8.64	$ 3.46	140,625	$ 3.46
$3.54 - $3.93	272,204	8.17	$ 3.76	108,297	$ 3.79
$3.96 - $4.26	273,830	7.74	$ 4.09	111,591	$ 4.06
$4.37 - $4.95	252,946	6.37	$ 4.76	198,805	$ 4.87
$4.98 - $5.59	253,358	6.81	$ 5.38	235,106	$ 5.39
$5.65 - $6.01	250,958	7.81	$ 5.80	121,774	$ 5.76
$6.06 - $7.50	258,249	7.62	$ 7.02	104,204	$ 6.97
$7.53 - $11.90	185,321	8.12	$ 11.12	74,004	$ 11.10
$13.09 - $13.09	8,000	9.94	$ 13.09	0	$ 0.00
$2.25 - $13.09	2,452,869	7.59	$ 5.09	1,265,639	$ 5.04

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, 2005, 786,743 shares had been sold under the Plan, leaving 213,077 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 June 30, 2007 unless extended by the Board of Directors. During the year ended December 31, 2005, the Company repurchased approximately 0.1 million shares under this program, at a cost of approximately $0.4 million.

Shares Reserved for Future Issuance. At December 31, 2005, approximately 4.3 million shares of common stock were reserved under our equity incentive plans, and 0.2 million were reserved for purchases under the ESPP.

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 2005 are as follows (in thousands):

	Operating Leases	Capital Leases
Years ending December 31,		
2006	$ 1,188	$ 1,406
2007	1,318	1,377
2008	1,453	1,404
2009	1,613	1,432
2010		1,461
Thereafter		6,142
Total minimum lease payments	$ 5,572	13,222
Less amount representing interest		(4,135)
Present value of capital lease payments		9,087
Less current portion		(648)
Long-term obligations under capital leases		$ 8,439

At December 31, 2005, assets under capital leases included in property and equipment totaled $12.9 million with accumulated amortization of $7.1 million.

Rent expense under operating leases totaled approximately $1.4 million, $1.5 million and $1.5 million for the years ended December 31, 2005, 2004 and 2003, respectively.

During December 1999, the Company completed a sale and leaseback transaction of one of its facilities. The facility was sold for $15.0 million, of which $3.8 million was capital contributed by the Company. The Company s lease for its 78,000 square foot facility 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 the years ended December 31, 2005, 2004 and 2003.

Contracts

Royalties. 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 1997 the Company paid an upfront cash payment of $2.3 million in conjunction with one of its license agreements. This license fee was capitalized and was being amortized over 7.5 years, until the completion of the agreement in 2004. In November 2005, the Company entered into a net cross-license agreement with a third party. Per the terms of the cross-license agreement, the Company paid $1.5 million during the fourth quarter of 2005, and the amount is being amortized on a straight-line basis through August 2006. As part of the Company s litigation settlement with Inverness Medical Innovations, Inc. (IMA), the Company entered into a royalty agreement with IMA

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 6. Commitments and Contingencies (Continued)

during 2005, which requires ongoing royalty payments of 8.5% on the majority of its products. Royalty expenses, which are charged to cost of sales under these licensing agreements, totaled $7.1 million, $5.6 million and $8.7 million for the years ended December 31, 2005, 2004 and 2003, respectively. As of December 31, 2005 and 2004, $3.4 million and $2.2 million, respectively, were recorded as accrued royalties in the accompanying consolidated balance sheets. The Company believes it will continue to incur substantial royalty expenses relating to future sales of its products.

Legal

As previously disclosed, beginning in February 2004, a number of legal proceedings were initiated by the Company and/or Inverness Medical Innovations (IMA) and/or its affiliates in Germany and the U.S. raising, among other issues, 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, Applied Biotech, Inc. (Applied), Armkel LLC (now Church & Dwight), Wampole Laboratories LLC (Wampole), Inverness Medical Switzerland (IMA Switzerland), and Unipath Diagnostics, Inc. (Unipath) were parties also involved in the legal proceedings.

In 2005, the Company entered into an agreement with IMA settling all domestic and international actions involving the Company, IMA, and IMA s affiliates (Applied, Wampole, IMA Switzerland and Unipath). Under the terms of the settlement agreement, the Company and IMA agreed to cross-license, and to cause their affiliates to cross-license, the parties respective lateral flow patent portfolios and to dismiss, and to cause their affiliates to dismiss, the parties respective cases. The Company agreed to make a net payment to IMA of $17.0 million and to pay net royalties of 8.5% on future sales of its current lateral flow products and future lateral flow products that utilize or incorporate any inventions claimed in the valid and enforceable claims of IMA lateral flow patents. The payment of the $17.0 million was made April 2005.

The Company s declaratory relief against Church and Dwight has not been settled, nor has Church & Dwight s claim for patent infringement, which seeks damages against the Company for over-the-counter sales and preliminary and permanent injunctions in the over-the-counter market.

There is not a specific amount or range sought in damages in the Church & Dwight lawsuit discussed above. Given the early stage of the action, the Company cannot predict the ultimate outcome of this matter at this time. As a result, in accordance with SFAS No. 5 Accounting for Contingencies, the Company has disclosed the existence of this lawsuit; however, no accrual for potential losses, if any, has been recorded.

The Company is also involved in other 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 26%, 29%, and 41% of net sales for the years ended December 31, 2005, 2004 and 2003, respectively. As of December 31, 2005 and 2004, balances due from foreign customers, in U.S. dollars, were $6.3 million and $8.0 million, respectively.

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 7. Industry and Geographic Information (Continued)

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

	Year ended December 31,		
	2005	2004	2003
Customer:			
A	18%	16%	16%
B	17%	13%	29%
C	15%	15%	7%
D	14%	12%	6%

As of December 31, 2005 and 2004, accounts receivable from individual customers with balances due in excess of 10% of total accounts receivable totaled $9.3 million and $9.6 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,		
	2005	2004	2005	2004	2003
United States operations					
Domestic	$ 19,557	$ 20,174	$ 65,863	$ 53,872	$ 53,506
Foreign			22,868	21,733	33,713
Foreign operations		7		467	3,647
Total	$ 19,557	$ 20,181	$ 88,731	$ 76,072	$ 90,866

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

	Year ended December 31,		
	2005	2004	2003
Influenza	$ 33,412	$ 25,661	$ 37,477
Group A Strep	19,412	16,502	17,427
Pregnancy	19,292	16,499	16,995
Bone markers	5,241	4,989	5,339
H. pylori	3,015	3,032	3,039
Mononucleosis	1,475	1,245	1,176
Chlamydia	1,038	1,481	1,213
Other products	5,846	6,663	8,200
	$ 88,731	$ 76,072	$ 90,866

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 $0.4 million, $0.4 million and $0.2 million to the 401(k) Plan during the years ended December 31, 2005, 2004 and 2003, respectively.

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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

	December 31,		
	2005	2004	2003
Net sales from discontinued operations			
Urinalysis	$ 572	$ 1,573	$ 2,116
Ultrasonometer		263	526
Total	$ 572	$ 1,836	$ 2,642
Loss from discontinued operations, net of taxes			
Loss from operations			
Urinalysis	$ (835)	$ (1,823)	$ (1,593)
Ultrasonometer	(97)	(80)	(90)
	(932)	(1,903)	(1,683)
Loss on asset impairment			
Urinalysis		(5,193)	
Ultrasonometer		(775)	
		(5,968)	
Total	$ (932)	$ (7,871)	$ (1,683)

Assets and liabilities of the urinalysis and ultrasonometer businesses are presented in the following table (in thousands):

	December 31	
	2005	2004
Assets held for sale, current		
Assets held for sale urinalysis	$	$ 908
Liabilities of discontinued operations urinalysis		(155)
Total	$	$ 753

QUIDEL CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 10. Quarterly Financial Information (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
	(in thousands, except per share data)				
2005					
Total revenues	$ 22,666	$ 14,823	$ 20,032	$ 34,778	$ 92,299
Gross profit	13,157	6,778	10,413	21,282	51,630
Earnings (loss) from continuing operations	(17,655)	(1,255)	816	9,767	(8,327)
Earnings (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)
2004(1)					
Total revenues	$ 19,326	$ 13,824	$ 13,612	$ 31,929	$ 78,691
Gross profit	9,658	6,624	5,799	18,757	40,838
Earnings (loss) from continuing operations	780	(1,702)	(3,521)	6,027	1,584
Loss from discontinued operations, net of taxes	(488)	(588)	(124)	(6,671)	(7,871)
Net earnings (loss)	292	(2,290)	(3,645)	(644)	(6,287)
Basic earnings (loss) per share:					
Continuing operations	0.03	(0.05)	(0.11)	0.19	0.05
Discontinued operations	(0.02)	(0.02)	(0.01)	(0.21)	(0.25)
Net earnings (loss)	0.01	(0.07)	(0.12)	(0.02)	(0.20)
Diluted earnings (loss) per share:					
Continuing operations	0.03	(0.05)	(0.11)	0.19	0.05
Discontinued operations	(0.02)	(0.02)	(0.01)	(0.21)	(0.25)
Net earnings (loss)	0.01	(0.07)	(0.12)	(0.02)	(0.20)

(1) The first three quarters during 2004 have been restated to reflect discontinued operations, which occurred in the fourth quarter of 2004.

SCHEDULE II

QUIDEL CORPORATION
CONSOLIDATED VALUATION AND QUALIFYING ACCOUNTS
(in thousands)

Description	Additions Balance at beginning of period	Charges to costs and expenses	Charges to other accounts	Deductions	Balance at end of period
Year ended December 31, 2005:					
Allowance(1)	$ 1,308	$ 2,080		$ 2,306	$ 1,082
Year ended December 31, 2004:					
Allowance(1)	2,006	2,278		2,976	1,308
Year ended December 31, 2003:					
Allowance(1)	872	2,156		1,022	2,006

(1) Represents provisions primarily related to returned goods allowances and defective products, allowances for cash discounts, contract pricing rebates, and bad debts, all of which are reductions to sales excluding bad debts. For the year ended December 31, 2005, $0.3 million, $0.9 million, $0.8 million and $0.1 million were charged to returned goods allowances and defective products, cash discounts, contract pricing rebates and bad debts, respectively. For the year ended December 31, 2004, $1.3 million, $0.7 million, $0.1 million and $0.1 million were charged to returned goods allowances and defective products, cash discounts, contract pricing rebates and bad debts, respectively. For the year ended December 31, 2003, $0.9 million, $0.6 million, $0.6 million and $0.1 million were charged to returned goods allowances and defective products, cash discounts, contract pricing rebates and bad debts, respectively.

EXHIBIT INDEX

Exhibit Number	Description
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 May 24, 2002 between Quidel Corporation and American Stock Transfer and Trust Company, as Rights Agent. (Incorporated by reference to Exhibit 1 to the Registrant s Current Report on Form 8-K filed on May 29, 2002.)
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	Trademark License Agreement dated October 1, 1994 between the Registrant and Becton, Dickinson and Company regarding the Q-Test trademark. (Incorporated by reference to Exhibit 10.15 to the Registrant s Form 10-K for the year ended March 31, 1995.)
10.8	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.)
10.9	Campbell License Agreement effective April 1, 1997 between the Registrant and Becton, Dickinson and Company. (Incorporated by reference to Exhibit 10.19 to the Registrant s Form 10-K for the year ended March 31, 1997.)
10.10	Rosenstein License Agreement effective April 1, 1997 between the Registrant and Becton, Dickinson and Company. (Incorporated by reference to Exhibit 10.20 to the Registrant s Form 10-K for the year ended March 31, 1997.)
10.11	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.)
10.12	Form of Single Tenant Absolute Net Lease. (Incorporated by reference to Exhibit 10.7 to the Registrant s Form 8-K filed on January 4, 2000.)
10.13	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.)

10.14(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.)
10.15(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.)
10.16(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.)
10.17(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.)
10.18(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.)
10.19(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.)
10.20(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.)
10.21(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.)
10.22(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.)
10.23(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.)
10.24(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.)
10.25(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.)
10.26(1)	Agreement Re: Change in Control, entered into on June 13, 2005, between Registrant and Robert J. Bujarski, J.D. (Incorporated by reference to Exhibit 10.2 to the Registrant s Form 8-K filed on June 17, 2005.)
10.27(1)	Annual Base Salary for the Company s Executive Officers effective as of March 6, 2006. (Incorporated by reference to Exhibit 10.1 to the Registrant s Form 8-K filed on March 3, 2006.)
10.28(1)	Registrant s Director Compensation Program, effective May 19, 2005. (Incorporated by reference to Exhibit 10.2 to the Registrant s Form 8-K filed on May 25, 2005.)
10.29(1)	Registrant s 2006 Short-Term Cash Incentive Plan. (Incorporated by reference to Exhibit 10.2 to the Registrant s Form 8-K filed on March 3, 2006.)

10.30	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.)
10.31	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.)
10.32	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.)
10.33	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).
10.34	Settlement Agreement dated April 27, 2005 between the Registrant and Inverness Medical Innovations, Inc. (Incorporated by reference to Exhibit 10.1 to the Registrants Form 8-K filed on May 3, 2005.)
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 Chief Financial Officer of Registrant pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications by Chief Executive Officer and Chief Financial Officer of Registrant pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Filed herewith

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