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 acquisit