QUIDEL CORP /DE/
Form 10-Q
May 10, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2006

or

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

For the transition period from 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)
(858) 552-1100
(Registrant s telephone number, including area code)

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 whether the Registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and non-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

As of May 5, 2006, 34,113,686 shares of common stock were outstanding.

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PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

QUIDEL CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands; unaudited)

	March 31, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,803	$ 34,930
Accounts receivable, net	13,497	15,819
Inventories, net	8,069	8,500
Other current assets	2,207	1,354
Total current assets	63,576	60,603
Property and equipment, net	19,760	19,557
Intangible assets, net	22,850	23,964
Deferred tax asset	8,864	8,864
Other non-current assets	783	860
Total assets	$ 115,833	$ 113,848
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,998	$ 5,134
Accrued royalties	2,368	3,367
Current portion of obligations under capital leases	650	648
Other accrued liabilities	5,466	7,470
Total current liabilities	12,482	16,619
Deferred rent	1,511	1,547
Capital leases, net of current portion	8,276	8,439
Stockholders equity:		
Common stock	34	34
Deferred stock compensation		(1,947)
Additional paid-in capital	160,704	161,662
Accumulated other comprehensive earnings	1,330	1,326
Accumulated deficit	(68,504)	(73,832)
Total stockholders equity	93,564	87,243
Total liabilities and stockholders equity	$ 115,833	$ 113,848

See accompanying notes.

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

	Three months ended March 31, 2006	2005
REVENUES		
Net sales	$ 26,673	$ 21,524
Research contracts, license fees and royalty income	377	1,142
Total revenues	27,050	22,666
COSTS AND EXPENSES		
Cost of sales	10,514	8,367
Research and development	3,279	3,350
Sales and marketing	4,058	4,289
General and administrative	2,952	3,989
Patent litigation settlement		17,000
Amortization of intangibles	1,065	315
Total costs and expenses	21,868	37,310
Operating earnings (loss)	5,182	(14,644)
OTHER INCOME (EXPENSE)		
Interest income	317	190
Interest expense	(194)	(206)
Other income (expense)	23	5
Total other income (expense)	146	(11)
Earnings (loss) from continuing operations before provision for income taxes	5,328	(14,655)
Provision for income taxes		3,000
Earnings (loss) from continuing operations	5,328	(17,655)
Loss from discontinued operations, net of taxes		(196)
Net earnings (loss)	$ 5,328	$ (17,851)
Basic earnings (loss) per share:		
Continuing operations	$ 0.16	$ (0.55)
Discontinued operations		(0.01)
Net earnings	0.16	(0.56)
Diluted earnings (loss) per share:		
Continuing operations	$ 0.15	$ (0.55)
Discontinued operations		(0.01)
Net earnings	0.15	(0.56)
Shares used in basic per share calculation	33,269	31,906
Shares used in diluted per share calculation	34,708	31,906

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands; unaudited)

	Three months ended March 31, 2006	2005
OPERATING ACTIVITIES:		
Earnings (loss) from continuing operations	$ 5,328	$ (17,655)
Adjustments to reconcile net earnings (loss) to net cash provided by operating activities:		
Depreciation and amortization	2,012	1,334
Stock-based compensation expense	633	119
Deferred income taxes		3,217
Changes in assets and liabilities:		
Accounts receivable	2,322	5,114
Inventories	431	942
Prepaid expenses and other current assets	(853)	(421)
Accounts payable	(1,136)	247
Accrued royalties	(999)	(1,117)
Accrued patent litigation		17,000
Other accrued liabilities	(1,962)	(909)
Net cash provided by continuing operations	5,776	7,871
Net cash used by discontinued operations		(61)
Net cash provided by operating activities	5,776	7,810
INVESTING ACTIVITIES:		
Acquisition of property, plant and equipment	(1,125)	(254)
Other assets	54	(178)
Net cash used for investing activities	(1,071)	(432)
FINANCING ACTIVITIES:		
Payments on capital lease obligation	(161)	(143)
Proceeds from issuance of stock under stock plans	325	368
Net cash provided by financing activities	164	225
Effect of exchange rate changes on cash and cash equivalents	4	(32)
Net increase in cash and cash equivalents	4,873	7,571
Cash and cash equivalents, beginning of period	34,930	36,322
Cash and cash equivalents, end of period	$ 39,803	$ 43,893
Supplemental disclosures of cash flow information:		
Cash paid during the period for interest	$ 194	$ 207
Cash paid during the period for income taxes	$	$

See accompanying notes.

Quidel Corporation
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Note 1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Quidel Corporation and its subsidiaries (the Company) have been prepared in accordance with generally accepted accounting principles in the U.S. for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the U.S. for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation (consisting of normal recurring accruals) have been included. The information at March 31, 2006, and for the three months ended March 31, 2006 and 2005, is unaudited. Operating results for the three months ended March 31, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. For further information, refer to the consolidated financial statements and footnotes thereto for the year ended December 31, 2005 included in the Company s 2005 Annual Report on Form 10-K.

The Company s first, second and third fiscal quarters end on the Sunday closest to March 31, June 30 and September 30, respectively. For ease of reference, the calendar quarter end date is used herein. The three month periods ended March 26, 2006 and March 27, 2005 both included 12 weeks.

Note 2. Comprehensive Earnings (Loss)

The components of comprehensive earnings (loss) are as follows (in thousands; unaudited):

	Three months ended March 31, 2006	**2005**
Net earnings (loss)	$ 5,328	$ (17,851)
Foreign currency translation adjustment	4	(32)
Comprehensive earnings (loss)	$ 5,332	$ (17,883)

Note 3. Computation of Earnings Per Share

Basic earnings per share were computed by dividing net earnings by the weighted-average number of common shares outstanding during the period. Diluted earnings per share reflects the potential dilution that could occur if the earnings were divided by the weighted-average number of common shares and potentially dilutive common shares from outstanding stock options. Potential dilutive common shares were calculated using the treasury stock method and represent incremental shares issuable upon exercise of the Company s outstanding stock options. Potentially dilutive shares have not been included for the three months ended March 31, 2005, as their inclusion would be anti-dilutive.

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

	Three months ended March 31, 2006	2005
Shares used in basic earnings per share (weighted-average common shares outstanding)	33,269	31,906
Effect of dilutive stock options	1,439	
Shares used in diluted earnings per share calculation	34,708	31,906

Note 4. Inventories

Inventories are recorded at the lower of cost (first-in, first-out) or market and consist of the following (in thousands):

	March 31, 2006 (unaudited)	December 31, 2005
Raw materials	$ 3,615	$ 3,414
Work-in-process	2,632	2,682
Finished goods	1,822	2,404
	$ 8,069	$ 8,500

Note 5. Income Taxes

The Company did not recognize income tax expense for the three months ended March 31, 2006 as the income tax provision for such periods was offset by an income tax benefit from previously reserved deferred tax assets. The Company does not anticipate recording a tax provision during 2006 as it anticipates that any current tax provision will be adjusted by the recognition of an offsetting amount on previously reserved deferred tax assets.

During the three months ended March 31, 2005, the Company recorded a patent litigation settlement charge of $17 million and, under the terms of the settlement, the Company is required to pay net 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 the Company s subsequent estimates of projected earnings, related primarily to the effect of the settlement payment and ongoing net royalty payments, partially offset by a projected reduction in future litigation expenses, the Company concluded that it could not support the recognition of the same level of deferred tax assets that it had reported on its balance sheet as 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, 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 its 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. 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 on estimates of future earnings, the Company determines 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.

Note 6. Stockholders Equity

During the three months ended March 31, 2006, 271,526 shares of restricted stock were awarded, 36,473 shares of common stock were issued due to the exercise of stock options and 23,165 shares of common stock were issued in connection with the Company s employee stock purchase plan, resulting in proceeds to the Company of approximately $0.3 million.

Note 7. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented $4.7 million (18%) and $2.8 million (13%) of net sales for the three months ended March 31, 2006 and 2005, respectively. As of March 31, 2006 and December 31, 2005, balances due from foreign customers were $2.2 million and $6.3 million, respectively.

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

	Three months ended March 31,	
	2006	**2005**
Customer:		
A	20 %	24 %
B	17 %	21 %
C	16 %	20 %
D	11 %	3 %

As of March 31, 2006, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled $9.0 million while, at December 31, 2005, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled $9.3 million.

Note 8. Stock-Based Compensation

The Company grants stock-based awards 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. Stock-based awards under these plans consist of stock option awards (stock options) and restricted stock awards (stock awards). The Company also issues stock under the Company s 1983 Employee Stock Purchase Plan (the ESPP). A more detailed description of these plans can be found in the Company s 2005 Annual Report on Form 10-K.

Prior to January 1, 2006, the Company followed 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 equaled or exceeded the estimated market price of the underlying stock on the date of grant, no compensation expense was recognized.

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

The Company s net earnings for the three months ended March 31, 2006 includes $0.6 million of compensation expense related to the Company s stock-based compensation plans. Compensation expense includes $0.4 million and $0.2 million related to stock options and stock awards, respectively. Compensation costs capitalized to inventory and compensation expense related to the Company s ESPP were not material for the three months ended March 31, 2006. The compensation expense related to the Company s stock-based compensation plans is included in the statement of operations as the following: cost of sales of $0.1 million; research and development of $0.1 million; sales and marketing of $0.1 million; and general and administrative of $0.3 million. The adoption of FAS 123R reduced net earnings for the three months ended March 31, 2006 by approximately $0.4 million. As a result, basic and diluted earnings per share were both reduced by $0.01 per share.

Stock Options

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

	Three months ended March 31,	
	2006	**2005**
Expected option life	4.54	6.2
Volatility rate	0.76	0.81
Risk-free interest rate	4.35 %	3.00 %
Forfeiture rate	12.7 %	0 %
Dividend rate	0 %	0 %

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

The Company s determination of fair value is affected by the Company s stock price as well as a number of assumptions that require judgment. The weighted-average fair value of each option granted during the three months ended March 31, 2006, estimated as of the grant date using the Black-Scholes option valuation model, was $7.44 per option. The total intrinsic value of options exercised was $0.2 million during the three months ended March 31, 2006. Intrinsic value is measured using the fair market value at the date of exercise (for shares exercised) or at March 31, 2006 (for outstanding options), less the applicable exercise price. As of March 31, 2006, total unrecognized compensation cost related to stock options was approximately $4.1 million and the related weighted-average period over which it is expected to be recognized is approximately 2.43 years.

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

	Number of shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2005	2,453	$ 5.09		
Granted	162	$ 11.97		
Exercised	(36)	$ 4.84		
Forfeited	(8)	$ 7.93		
Outstanding at March 31, 2006	2,571	$ 5.52	7.54	$ 18,760
Vested and expected to vest at March 31, 2006	2,377	$ 5.43	7.43	$ 17,661
Exercisable at March 31, 2006	1,367	$ 5.02	6.63	$ 10,664
Available for future grant at March 31, 2006	852			

Stock Awards

The fair value of stock awards is determined based on the closing market price of the Company s common stock on the grant date. Compensation expense for stock awards is measured at the grant date and recognized ratably over the vesting period. For stock awards granted prior to December 31, 2005, vesting is based on both the service period as well as the achievement of company performance goals. Meeting the performance goals for these awards allows for acceleration of a portion of the awards. The stock awards granted in March 2006 were all performance based and vesting is tied to achievement of company goals. For purposes of measuring compensation expense, the amount of shares ultimately expected to vest is estimated at each reporting date based on management s expectations regarding the relevant performance criteria.

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

	Number of shares	Weighted-average grant-date fair value per share
Nonvested at December 31, 2005	553	$ 4.44
Awarded	272	$ 12.12
Vested	(2)	$ 7.49
Forfeited	0	$
Nonvested at March 31, 2006	823	$ 6.97

Stock-based compensation expense related to stock awards outstanding during the three months ended March 31, 2006 and 2005 was approximately $0.2 and $0.1 million, respectively. As part of the adoption of FAS 123R, the deferred compensation costs of $1.9 million at December 31, 2005 were reclassified as a reduction of additional paid-in capital beginning January 1, 2006. The total amount of unrecognized compensation cost related to nonvested stock awards as of March 31, 2006 was approximately $5.0 million, which is expected to be recognized over a weighted-average period of approximately 3.1 years.

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

	Three months ended March 31, 2005
Net loss, as reported	$ (17,851)
Add: Stock-based compensation expense included in reported net loss, net of related tax effects	119
Deduct: Stock-based compensation expense determined under fair value-based method for all awards, net of related tax effects	(805)
Pro forma net loss	$ (18,537)
Basic and diluted loss per share as reported	$ (0.56)
Basic and diluted loss per share pro forma	$ (0.58)

Note 9. Commitments and Contingencies

Legal

As previously disclosed, beginning in February 2004, a number of legal proceedings were initiated by the Company 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 and IMA s affiliates, Armkel LLC (now Church & Dwight, Co., Inc.) (Church & Dwight) was also a party involved in the legal proceedings.

In April 2005, the Company entered into an agreement with IMA settling all domestic and international actions involving IMA and IMA s affiliates. 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 the Company s 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.

On March 10, 2006, the Company entered into a strategic business partnership with Church & Dwight and settled the pending intellectual property litigation between the Company and Church & Dwight. In connection with the settlement with Church & Dwight, the Company and Church & Dwight agreed to cross-license certain patents related to lateral flow technology for the over-the-counter market.

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

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 the Company s business.

ITEM 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

In this quarterly report, all references to we, our and us refer to Quidel Corporation and its subsidiaries.

Future Uncertainties

This report contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, seasonality, the length and severity of cold and flu seasons, uncertainty surrounding the detection of novel influenza viruses involving human specimens, adverse changes in the competitive and economic conditions in domestic and international markets, actions of our major distributors, manufacturing and production delays or difficulties, adverse actions or delays in product reviews by the U.S. Food and Drug Administration (FDA), intellectual property, product liability, environmental or other litigation, and lower than anticipated sales or market penetration of our new products. Forward-looking statements typically are identified by the use of terms such as may, will, should, might, expect, anticipate, estimate and similar words, although some forward-looking statemen expressed differently. The risks described under Risk Factors in Part II, Item 1A of this report and elsewhere herein and in reports and registration statements that we file with 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 report. The following should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included elsewhere in this report. We undertake no obligation to publicly release the results of any revision or update of these forward-looking statements.

Overview

We enjoy a leadership position in the development, manufacturing and marketing of rapid diagnostic solutions at the point of care (POC) in infectious diseases and reproductive health. We focus on POC testing solutions specifically developed for the physician office lab and acute care markets globally. We primarily earn revenue from sales of products for use in physician offices, hospitals, clinical laboratories and wellness screening centers. We market our products in the U.S. through a network of national and regional distributors, supported by a direct sales force. Internationally, we sell and market primarily in Japan and Europe by channeling products through distributor organizations and sales agents.

Our product sales increased to $26.7 million for the three months ended March 31, 2006 from $21.5 million for the three months ended March 31, 2005. This was largely driven by increased sales of our influenza product to the Japanese market and increased domestic sales of our influenza, Group A Strep and pregnancy tests as we continued to focus our efforts to strengthen market and brand leadership in infectious disease and reproductive health by delivering economic and clinical proof through our efforts with our Quidel Value Build (QVB) program.

We derive a significant portion of our net sales from three product lines. For the three months ended March 31, 2006 and 2005, we derived approximately 85% and 84%, respectively, of our net sales from sales of our influenza, Group A Strep and pregnancy tests. 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. Approximately 64% and 73% of our net sales for the three months ended March 31, 2006 and 2005, respectively, were derived from sales through our four largest distributors.

Recent Developments

On March 10, 2006, we entered into a strategic business partnership with Church & Dwight Co., Inc. (Church & Dwight) and settled the pending intellectual property litigation between Church & Dwight and us. In connection with this settlement, we also agreed to a cross-licensing arrangement with Church & Dwight pertaining to certain patents related to lateral flow technology for the over-the-counter market. Also refer to the discussion in Legal Proceedings in Part II, Item 1 of this report.

Outlook

For the remainder of 2006, we anticipate continued year-over-year 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 net impact of the change in our royalty component. We expect continued growth in revenues 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.

You should also refer to the discussion in Item 1.A, Risk Factors in Part II of this report for further discussion of risks related to our business.

Results of Operations

Net Sales

Net sales increased 24% to $26.7 million for the three months ended March 31, 2006 from $21.5 million for the three months ended March 31, 2005. The increase was largely driven by increases in sales of our influenza, Group A Strep and pregnancy products of $3.3 million, $1.4 million and $0.3 million, respectively. These three product lines accounted for 85% of our net sales for three months ended March 31, 2006 compared to 84% for three months ended March 31, 2005.

We believe revenue related to these core products has continued to increase due to successes related to our QVB, which have resulted in strengthened customer relationships and preferred partnership programs.

Additionally, the increase in sales of our influenza products was primarily related to our Japanese market and the continued success domestically of our new influenza A+B product. For the three months ending March 31, 2005, we experienced a significant decrease in sales of our influenza products to the Japanese market. This was the result of a weak flu season in 2004, and resulted in excess quantities of our influenza A/B product in our Japanese distribution channel. As a result, our sales were adversely and materially affected during the first quarter of 2005. During 2005, the inventory levels in the Japanese market were reduced, resulting in increased sales in the first quarter of 2006. Our influenza products have an estimated 66% market share in the U.S., where we are the market leader. Also, the increase in sales of our Group Strep A and pregnancy products was primarily related to increased domestic sales, which were driven by increased volume as well as higher average selling prices. Our U.S. professional market share is an estimated 46% and 50% for our Group Strep A and pregnancy products, respectively, and we are the market leader in both.

Research Contracts, License Fees and Royalty Income

Research contracts, license fees and royalty income decreased to $0.4 million for the three months ended March 31, 2006 from $1.1 million for the three months ended March 31, 2005. This decrease was primarily related to $0.7 million of research contract revenue that we earned during the three months ended March 31, 2005 in connection with achieving certain milestones under a joint development agreement with another company. During the second quarter of 2005, the joint development agreement was terminated. The remaining balance for the three months ended March 31, 2006 and 2005 relates to royalty payments received on a patented technology of ours utilized by a third party. The agreement covering the royalty payments extends through November 2009, the expiration date of the patent.

Cost of Sales and Gross Profit from Net Sales

Gross profit from net sales increased to $16.2 million for the three months ended March 31, 2006 from $13.2 million for the three months ended March 31, 2005. Gross profit from net sales as a percentage of net sales was 61% for both the three months ended March 31, 2006 and 2005. The three months ended March 31, 2006 was impacted favorably by increased volume, a more favorable product mix, and an increase in average selling prices. This was offset by an increase in royalty expense due primarily to the 8.5% royalty we began paying on the majority of our products during the second quarter of 2005 related to the patent litigation settlement with Inverness Medical Innovations, Inc. (IMA) as discussed elsewhere in this report. In connection with the patent litigation settlement entered into during the second quarter of 2005, we are required, as of May 2005, to pay an 8.5% royalty on net sales of our influenza, Group A Strep, pregnancy, H-Pylori, mononucleosis, chlamydia, iFOB and veterinary products. These product sales accounted for 94% and 92% of our net sales for the three months ended March 31, 2006 and 2005, respectively, and will continue to represent a majority of our revenues for the foreseeable future. Royalty expense related to this agreement was $2.1 million for the three months ended March 31, 2006. We also experienced an increase in royalties due to an increase in sales to certain international markets, where we have historically incurred a 5.25% royalty on our lateral flow products. Royalty expense related to this agreement for the three months ended March 31, 2006 was $0.2 million.

Royalty expense was favorably impacted for the three months ended March 31, 2006 as we fulfilled the terms of an agreement with another party related to the development of our influenza product. We are no longer required to pay to this party a 6% royalty on sales of our influenza product, which resulted in a favorable impact to our royalty expense of $0.3 million for the three months ended March 31, 2006. Our influenza products sales accounted for 46% and 41% of our net sales for the three months ended March 31, 2006 and 2005, respectively.

Research and Development Expense

Research and development expense decreased to $3.3 million for the three months ended March 31, 2006 from $3.4 million for the three months ended March 31, 2005. Research and development expense as a percentage of net sales decreased to 12% of net sales for the three months ended March 31, 2006, as compared to 16% of net sales for the three months ended March 31, 2005. The primary components are personnel and project material costs related to our ongoing efforts with our Layered Thin Film (LTF) immunoassay technology, our new products under development (Respiratory Syncitial Virus (RSV) and new Metra® brand bone marker assays) as well as the transfer of our QuickVu A+B test onto our new, highly automated manufacturing process. In addition, we continue to incur substantial costs related to clinical trials as we support the areas noted above as well as our overall efforts for QVB.

Sales and Marketing Expense

Sales and marketing expense decreased to $4.1 million for the three months ended March 31, 2006 from $4.3 million for the three months ended March 31, 2005. Sales and marketing expense as a percentage of net sales decreased to 15% of net sales for the three months ended March 31, 2006, as compared to 20% of net sales for the three months ended March 31, 2005. We continue to invest in several key areas: baselining our brand equity, more in-depth analysis related to voice of customer surveys and expanding our communications through extensive advertising and public relations. Additionally, for the three months ended March 31, 2006, we had promotional costs associated with the recent launch of our iFOB test.

General and Administrative Expense

General and administrative expense decreased to $3.0 million for the three months ended March 31, 2006 from $4.0 million for the three months ended March 31, 2005. General and administrative expense as a percentage of net sales decreased to 11% for the three months ended March 31, 2006 from 19% for the three months ended March 31, 2005. The absolute dollar decrease for the three months ended March 31, 2006 was primarily due to decreased legal fees of $1.3 million resulting from the settlement of our intellectual property litigation with IMA in the first quarter of 2005. These decreases were offset by an increase in personnel related costs of $0.8 million related to stock compensation and management incentive plan costs for the three months ended March 31, 2006.

Patent Litigation Settlement

During the second quarter of 2005, we entered into an agreement to settle certain patent litigation as discussed in Part II, Item 1, Legal Proceedings and elsewhere in this report. In conjunction with the settlement with IMA, 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 also Note 9 of the Notes to Condensed Consolidated Financial Statements included in Part 1, Item 1 of this report.

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 in December 2005, and subsequently determined there were no impairment indicators as of March 31, 2006. 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 one to 12 years, include purchased technology, license agreements, patents, trademarks and a favorable lease.

Amortization expense increased to $1.1 million for the three months ended March 31, 2006 from $0.3 million for the three months ended March 31, 2005. The increase for the three months ended March 31, 2006 was due to the amortization of intellectual property related to two license agreements entered into during late 2005.

Other Income (Expense)

Interest income was $0.3 and $0.2 million for the three months ended March 31, 2006 and 2005, respectively, and relates primarily to interest earned on our cash and cash equivalents balance. Interest expense was $0.2 million for both the three months ended March 31, 2006 and 2005 and relates primarily to interest paid on obligations under capital leases, which are primarily related to our San Diego facility.

Income Taxes

We did not recognize income tax expense for the three months ended March 31, 2006 as the income tax provision for such periods was offset by an income tax benefit from previously reserved deferred tax assets. We do not anticipate recording a tax provision during 2006 as it anticipates that any current tax provision will be adjusted by the recognition of an offsetting amount on previously reserved deferred tax assets.

During the three months ended March 31, 2005, we recorded a patent litigation settlement charge of $17 million and, under the terms of the settlement, we are required to pay net 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 our subsequent estimates of projected earnings, related primarily to the effect of the settlement payment and ongoing net 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.

Loss from discontinued operations, net of taxes

In the accompanying financial statements, 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 were classified as discontinued operations in the statements of operations for the three months ended March 31, 2005.

Liquidity and Capital Resources

As of March 31, 2006, our principal source of liquidity consisted of $39.8 million in cash and cash equivalents. Our working capital as of March 31, 2006 was $51.1 million.

Our earnings from continuing operations provided cash of $5.8 million for the three months ended March 31, 2006. We had earnings from continuing operations of $5.3 million, including $2.0 million of depreciation and amortization of intangible assets. Other changes in operating assets and liabilities included a decrease in accounts receivable, inventory, accounts payable and accrued royalties of $2.3 million, $0.4 million, $1.1 million and $1.0 million, respectively, due to the seasonal decrease in net sales for the three months ended March 31, 2006 compared to the three months ended December 31, 2005. The decrease of $2.0 million in other current liabilities is primarily due to our scheduled $1.0 million payment related to the iFOB test product acquisition as well as payment of employee bonuses during the three months ended March 31, 2006.

Our investing activities used $1.1 million during the three months ended March 31, 2006. This included $0.7 million for building improvements and $0.4 million for the acquisition of production and scientific equipment.

We have approximately $2.0 million of firm purchase commitments with respect to the acquisition of the iFOB test as of the date of filing this report. These commitments largely relate to inventory component purchases relating to the iFOB test. We are planning approximately $4.0 million in capital expenditures for the remainder of 2006. The primary purpose for our capital expenditures is to acquire manufacturing equipment, implement facility expansion and improvements, and for information technology. We plan to fund these capital expenditures with cash flow from operations. We do not have any firm purchase commitments with respect to such planned expenditures as of the date of filing this report.

Our financing activities provided $0.2 million of cash during the three months ended March 31, 2006. This was primarily related to proceeds of $0.3 million received from the issuance of common stock under our equity incentive plans, partially offset by $0.2 million 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 March 31, 2006, 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 March 31, 2006, we did not have any relationships with unconsolidated entities or financial partners, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

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:

Prior to December 31, 2005, we accounted for our share-based employee compensation plans under the measurement and recognition provisions of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations, as permitted by Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation. We recorded no share-based employee compensation expense for options granted under our 2001 Equity Incentive Plan or its predecessor plans prior to December 31, 2005, as all options granted under those plans had exercise prices equal to or greater than the fair market value of our common stock on the date of grant. We did not have material compensation expense in connection with our Employee Stock Purchase Plan. In accordance with SFAS 123 and SFAS 148, Accounting for Stock-Based Compensation Transition and Disclosure, we disclosed our net earnings (loss) and net earnings (loss) per share as if we had applied the fair value-based method in measuring compensation expense for our share-based incentive programs.

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R), Share-Based Payment, using the modified prospective transition method. Under that transition method, compensation expense that we recognize beginning on that date includes: (a) compensation expense for all share-based payments granted prior to, but not yet vested as of December 31, 2005, based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation expense for all share-based payments granted on or after January 1, 2006 based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R). Results for prior periods have not been restated.

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

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. Change in title to the product and recognition of revenue occur upon delivery to the customer when sales terms are FOB destination and at the time of shipment when the sales terms are FOB shipping point. 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. 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 the 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 the carrying amount, including goodwill. If the fair value of a reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, goodwill is impaired and the loss is measured by performing step two. Under step two, the impairment loss is measured by comparing the implied fair value of the reporting unit with the carrying amount of goodwill. SFAS No. 142 requires periodic evaluations for impairment of goodwill balances. We completed our annual evaluation for impairment of goodwill in December 31, 2005 and subsequently determined there were no impairment indicators as of March 31, 2006.

We did not recognize income tax expense for the three months ended March 31, 2006 as the income tax provision for such periods was offset by an income tax benefit from previously reserved deferred tax assets. We do not anticipate recording a tax provision during 2006 as it anticipates that any current tax provision will be adjusted by the recognition of an offsetting amount on previously reserved 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 March 31, 2006 for which a valuation allowance was determined to be unnecessary will be realized in the ordinary course of operations based on the available positive and negative evidence, primarily our projected earnings. The amount of the net deferred tax assets considered realizable, however, could be reduced in the near term if actual future earnings or income tax rates are lower than estimated, or if there are differences in the timing or amount of future reversals of existing taxable or deductible temporary differences.

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 is made. Conversely, if based on estimates of future earnings, we determined that all or a portion of the valuation allowance is no longer warranted, a reduction in the valuation would result in a corresponding credit to additional paid-in capital, goodwill, and/or income tax expense in the period such determination is made.

ITEM 3. 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 March 31, 2006. Based on our market risk sensitive instruments outstanding at March 31, 2006 and 2005, we have determined that there was no material market risk exposure to our consolidated financial position, results of operations or cash flows as of such dates.

Our current investment policy with respect to our cash and cash equivalents focuses on maintaining acceptable levels of interest rate risk and liquidity. Although we continually evaluate our placement of investments, as of March 31, 2006, our cash and cash equivalents were placed in money market and/or overnight funds that are highly liquid and which we believe are not subject to material market fluctuation risk.

ITEM 4. 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 March 31, 2006 to provide reasonable assurance that information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

Changes in internal control over financial reporting. There was no change in our internal controls during the three months ended March 31, 2006 that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

PART II OTHER INFORMATION

ITEM 1. Legal Proceedings

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

In April 2005, we entered into an agreement with IMA settling all domestic and international actions involving IMA and IMA s affiliates. Under the terms of the settlement agreement, we and IMA agreed to cross-license, and to cause our and their affiliates to cross-license, the parties respective lateral flow patent portfolios and to dismiss, and to cause our and 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.

On March 10, 2006, we entered into a strategic business partnership with Church & Dwight and settled the pending intellectual property litigation between us and Church & Dwight. In connection with this settlement with Church & Dwight, we and Church & Dwight agreed to cross-license certain patents related to lateral flow technology for the over-the-counter market.

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 an upfront payment or payments 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 1A. Risk Factors

There are no material changes to the Risk Factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005 other than a change to the first risk factor below.

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 three months ended March 31, 2006, net sales increased 24% to $26.7 million from $21.5 million for the three months March 31, 2005. For further discussion of this increase, refer to Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations for Net Sales included in this 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 government and media attention focused on a potential influenza pandemic and the related potential impact on humans from avian flu, including the uncertainty surrounding the detection of novel influenza viruses in human specimens and the U.S. Government s recent report which focused on vaccination solutions and called for the development of new rapid diagnostic tests, which are not commercially available at this time, that identify specific strains of influenza and have greater sensitivity and specificity;

- changes in the level of competition, such as would occur if one of our larger and better financed competitors introduced a new or lower priced product to compete with one of our products;

- changes in 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.

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We 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 IMA and/or our or IMA S affiliates in Germany and the U.S. raising, among other items, issues of patent infringement, patent enforceability and patent invalidity relative to fundamental, lateral-flow technology. In legal proceedings in the U.S., in addition to IMA and IMA s affiliates, Church & Dwight was also a party involved in the legal proceedings.

In April 2005, we entered into an agreement with IMA settling all domestic and international actions involving IMA and IMA s affiliates. Under the terms of the settlement agreement, we and IMA agreed to cross-license, and to cause our and their affiliates to cross-license, the parties respective lateral flow patent portfolios and to dismiss, and to cause our and 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.

On March 10, 2006, we entered into a strategic business partnership with Church & Dwight and settled the pending intellectual property litigation between us and Church & Dwight. In connection with this settlement with Church & Dwight, we and Church & Dwight agreed to cross-license certain patents related to lateral flow technology for the over-the-counter market.

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 an upfront payment or payments 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 Specialty Products Group (the 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 RapidsTM.

As a result of any number of risk factors identified in this 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, accounted for approximately 64% and 73% of our net sales for the three months ended March 31, 2006 and 2005, 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% for 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 IMA, 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. 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 technologies and 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 18% and 12% of our net sales for the three months ended March 31, 2006 and 2005, respectively. International sales are subject to inherent economic, political and regulatory risks, which could increase our operating costs, result in shipment delays and impede our international growth. These foreign risks include:

- 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 2% increase in value of the Euro against the U.S. dollar for three months ended March 31, 2006. We also have exposure to the Japanese Yen, which did not materially change against the U.S. dollar for the three months ended March 31, 2006;

- longer payment cycles and greater difficulty in accounts receivable collection;

- reduced protection for, and enforcement of, intellectual property rights;

- political and economic instability in some of the regions where we currently sell our products or that we may expand into in the future;

- potentially adverse tax consequences; and

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

Currently, all of our international sales are negotiated for and paid in U.S. dollars. Nonetheless, these sales are subject to currency risks, since changes in the values of foreign currencies relative to the value of the U.S. dollar can render our products comparatively more expensive. These exchange rate fluctuations could negatively impact international sales of our products and our anticipated foreign operations, as could changes in the general economic conditions in those markets. In order to maintain a competitive price for our products in Europe and Japan, we may have to 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 their Annual Reports on Form 10-K that contains an assessment by management of the effectiveness of 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 stock-based 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 January 1, 2006 have been negatively and materially impacted by this accounting change. Other potential changes in existing taxation rules related to stock options and other forms of stock-based 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 March 31, 2005 and March 31, 2006, the 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 March 31, 2006:

- approximately 34.1 million shares of our common stock had been issued in registered offerings and 33.3 million are freely tradable in the public markets, and 0.8 million relate to restricted shares;
- approximately 2.6 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 $5.52; and
- we had in effect registration statements under the Securities Act of 1933 registering approximately 4.0 million shares of common stock reserved under our equity incentive plan. In addition, there were $0.2 million 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 our management.

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 our management. 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

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

	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 January 1, 2006	70,500	$ 4.95	70,500	$ 24,600,000
January 1 January 31, 2006				24,600,000
February 1 February 28, 2006				24,600,000
March 1 March 31, 2006				24,600,000
Ending balance March 31, 2006	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.

In addition to the stock repurchase program noted above, 374 shares of common stock, at a cost of $11.68 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 during the three months ended March 31, 2006.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. Exhibits

Exhibit Number	
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)	Executive officers 2006 Annual Base Salaries. (Incorporated by reference to Exhibit 10.1 to the Registrant s Form 8-K filed on March 3, 2006.)
10.2(1)	Executive officers 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.)
10.3(1)	Executive officers 2005 Cash Bonus Awards. (Incorporated by reference to Exhibit 10.3 to the Registrant s Form 8-K filed on March 3, 2006.)
10.4(1)	Executive officers 2006 Equity Award Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant s Form 8-K filed on March 23, 2006.)
10.5(1)	Form of 2006 Executive Officer Restricted Stock Award Agreement. (Incorporated by reference to Exhibit 10.2 to the Registrant s Form 8-K filed on March 23, 2006.)
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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 10, 2006

QUIDEL CORPORATION

/s/ CAREN L. MASON
Caren L. Mason
President and Chief Executive Officer
(Principal Executive Officer) and Director

/s/ PAUL E. LANDERS
Paul E. Landers
Senior Vice President, Finance and Administration,
Chief Financial Officer and Secretary
(Principal Financial Officer and Accounting Officer)

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