QUIDEL CORP /DE/
Form 10-Q
November 03, 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 September 30, 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 large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer x Non-accelerated filer o

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

As of October 19, 2006, 33,386,211 shares of common stock were outstanding.

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PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

QUIDEL CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands; unaudited)

	September 30, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,594	$ 34,930
Accounts receivable, net	15,303	15,819
Inventories, net	9,381	8,500
Prepaids and other current assets	1,582	1,354
Total current assets	56,860	60,603
Property and equipment, net	20,288	19,557
Goodwill	13,072	13,072
Purchased intangible assets, net	7,770	10,892
Deferred tax asset	8,864	8,864
Other non-current assets	659	860
Total assets	$ 107,513	$ 113,848
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,175	$ 5,134
Accrued payroll and related expenses	1,923	1,847
Accrued royalties	2,145	3,367
Current portion of obligations under capital leases	654	648
Other accrued liabilities	5,213	5,623
Total current liabilities	14,110	16,619
Capital leases, net of current portion	7,938	8,439
Deferred rent	1,438	1,547
Stockholders equity:		
Common stock	33	34
Deferred stock compensation		(1,947)
Additional paid-in capital	153,056	161,662
Accumulated other comprehensive earnings	1,348	1,326
Accumulated deficit	(70,410)	(73,832)
Total stockholders equity	84,027	87,243
Total liabilities and stockholders equity	$ 107,513	$ 113,848

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2006	2005	2006	2005
REVENUES				
Net sales	$ 23,436	$ 19,693	$ 66,310	$ 54,618
Research contracts, license fees and royalty income	284	339	931	2,903
Total revenues	23,720	20,032	67,241	57,521
COSTS AND EXPENSES				
Cost of sales	10,344	9,280	29,527	24,270
Research and development	3,126	2,968	9,903	9,304
Sales and marketing	4,080	3,610	12,312	11,776
General and administrative	3,322	2,531	9,547	9,577
Patent litigation settlement				17,000
Amortization of intangibles	849	315	2,979	945
Total costs and expenses	21,721	18,704	64,268	72,872
Operating earnings (loss)	1,999	1,328	2,973	(15,351)
OTHER (INCOME) EXPENSE				
Interest expense	188	201	573	611
Interest income	(346)	(155)	(1,070)	(519)
Other	14	(1)	48	(13)
Total other (income) expense	(144)	45	(449)	79
Earnings (loss) from continuing operations before provision for income taxes	2,143	1,283	3,422	(15,430)
Provision for income taxes		467		2,664
Earnings (loss) from continuing operations	2,143	816	3,422	(18,094)
Loss from discontinued operations, net of taxes		(116)		(767)
Net earnings (loss)	$ 2,143	$ 700	$ 3,422	$ (18,861)
Basic earnings (loss) per share:				
Continuing operations	$ 0.07	$ 0.02	$ 0.10	$ (0.56)
Discontinued operations	0.00	0.00	0.00	(0.02)
Net earnings (loss)	0.07	0.02	0.10	(0.58)
Diluted earnings (loss) per share:				
Continuing operations	$ 0.06	$ 0.02	$ 0.10	$ (0.56)
Discontinued operations	0.00	0.00	0.00	(0.02)
Net earnings (loss)	0.06	0.02	0.10	(0.58)
Shares used in basic per share calculation	32,551	32,808	33,060	32,330
Shares used in diluted per share calculation	33,744	33,787	34,400	32,330

See accompanying notes.

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

	Nine months ended September 30, 2006	2005
OPERATING ACTIVITIES:		
Net earnings (loss)	$ 3,422	$ (18,861)
Loss from discontinued operations		767
Earnings (loss) from continuing operations	3,422	(18,094)
Adjustments to reconcile net earnings (loss) to net cash provided by (used by) operating activities:		
Depreciation and amortization	6,146	3,949
Loss on disposal of property plant and equipment	15	8
Stock-based compensation expense	2,535	591
Deferred income taxes		2,757
Changes in assets and liabilities:		
Accounts receivable	516	2,032
Inventories	(881)	(176)
Prepaid expenses and other current assets	(228)	82
Accounts payable	(959)	(437)
Accrued royalties	(1,222)	(266)
Other accrued liabilities	(441)	1,319
Net cash provided by (used by) continuing operations	8,903	(8,235)
Net cash provided by discontinued operations		(14)
Net cash provided by (used by) operating activities	8,903	(8,249)
INVESTING ACTIVITIES:		
Acquisition of property, plant and equipment	(3,680)	(1,419)
Acquisition of intangible assets		(5,600)
Other assets	132	(186)
Net cash used for investing activities	(3,548)	(7,205)
FINANCING ACTIVITIES:		
Payments on capital lease obligations	(495)	(438)
Payments to repurchase common stock	(11,558)	(352)
Proceeds from issuance of stock under stock plans	2,340	4,320
Net cash provided by (used by) financing activities	(9,713)	3,530
Effect of exchange rate changes on cash and cash equivalents	22	(70)
Net decrease in cash and cash equivalents	(4,336)	(11,994)
Cash and cash equivalents, beginning of period	34,930	36,322
Cash and cash equivalents, end of period	$ 30,594	$ 24,328
Supplemental disclosures of cash flow information:		
Cash paid during the period for interest	$ 573	$ 611
Cash paid during the period for income taxes	$	$

See accompanying notes.

Quidel Corporation
Notes to 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 September 30, 2006, and for the three and nine months ended September 30, 2006 and 2005, is unaudited. Operating results for the three and nine months ended September 30, 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 and nine-month periods ended September 24, 2006 and September 25, 2005 included 13 weeks and 38 weeks, respectively.

Note 2. Comprehensive Earnings (Loss)

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

	Three months ended September 30,		**Nine months ended September 30,**	
	2006	**2005**	**2006**	**2005**
Net earnings (loss)	$ 2,143	$ 700	3,422	$ (18,861)
Foreign currency translation adjustment	3	(1)	22	(69)
Comprehensive earnings (loss)	$ 2,146	$ 699	3,444	$ (18,930)

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 as well as unvested restricted stock awards. Potential dilutive common shares were calculated using the treasury stock method and represent incremental shares issuable upon exercise of the Company s outstanding stock options and unvested restricted stock awards. The Company has awarded restricted stock with both service-based as well as performance-based vesting provisions. Stock awards based on performance only are not included in the calculation of earnings per share until the performance criteria are met. Potentially dilutive shares have not been included in the periods in which the Company recorded a net loss, 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 September 30,		Nine months ended September 30,	
	2006	2005	2006	2005
Shares used in basic earnings per share (weighted-average common shares outstanding)	32,551	32,808	33,060	32,330
Effect of dilutive stock options and restricted stock awards	1,193	979	1,340	
Shares used in diluted earnings per share calculation	33,744	33,787	34,400	32,330

Note 4. Inventories

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

	September 30, 2006 (unaudited)	December 31, 2005
Raw materials	$ 3,258	$ 3,414
Work-in-process	3,508	2,682
Finished goods	2,615	2,404
	$ 9,381	$ 8,500

Note 5. Income Taxes

The Company did not recognize income tax expense for the three and nine months ended September 30, 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 $17.0 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 nine months ended September 30, 2006, 271,526 shares of restricted stock were awarded, 448,987 shares of common stock were issued due to the exercise of stock options and 38,393 shares of common stock were issued in connection with the Company s employee stock purchase plan, resulting in proceeds to the Company of approximately $2.3 million. Additionally, 1,221,130 shares of outstanding common stock were repurchased for approximately $11.6 million.

Note 7. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented $12.6 million (19%) and $12.0 million (22%) of net sales for the nine months ended September 30, 2006 and 2005, respectively. As of September 30, 2006 and December 31, 2005, balances due from foreign customers were $4.6 million and $6.3 million, respectively.

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

	Nine months ended September 30,	
	2006	2005
Customer:		
A	19 %	23 %
B	17 %	13 %
C	16 %	16 %
D	11 %	7 %
E	11 %	11 %

As of September 30, 2006, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled $11.1 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 (the 2001 Plan) and previously granted options under the 1998 Stock Incentive Plan and the 1996 Non-Employee Directors Stock Option Plan. The 1998 and 1996 Plans were terminated at the time of adoption of the 2001 Plan, but the terminated Plans continue to govern outstanding stock 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 and director stock options. Under APB No. 25, because the exercise price of the Company s employee and director stock options equaled or exceeded the estimated market price of the underlying stock on the date of grant, no compensation expense was recognized.

Effective January 1, 2006, the Company began recording compensation expense associated with stock options in accordance with SFAS No. 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 nine 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 September 30, 2006 includes $0.5 million and $0.4 million of compensation expense related to stock options and stock awards, respectively. The Company s net earnings for the nine months ended September 30, 2006 includes $1.4 million and $1.1 million of compensation expense related to stock options and stock awards, respectively. The compensation expense related to the Company s stock-based compensation plans is included in the statement of operations for the three and nine months ended September 30, 2006 as follows: cost of sales of $0.1 million and $0.3 million, respectively; research and development of $0.2 million and $0.5 million, respectively; sales and marketing of $0.1 million and $0.3 million, respectively; and general and administrative of $0.6 million and $1.5 million, respectively. The adoption of FAS 123R decreased net earnings for the three and nine months ended September 30, 2006 by approximately $0.5 million and $1.4 million, respectively. As a result, basic and diluted earnings per share for the three and nine months ended September 30, 2006 were reduced by $0.02 and $0.04 per share, respectively.

Compensation costs capitalized to inventory and compensation expense related to the Company s ESPP were not material for the three and nine months ended September 30, 2006.

Stock Options

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

	Three months ended September 30,		**Nine months ended September 30,**	
	2006	**2005**	**2006**	**2005**
Expected option life	4.62	4.60	4.55	4.60
Volatility rate	.73	.80	.75	.80
Risk-free interest rate	5.05 %	3.4 %	4.64 %	3.4 %
Forfeiture rate	12.7 %	0 %	12.7 %	.0 %
Dividend rate	0 %	0 %	0 %	0 %

The computation of the expected option life is based on a weighted-average calculation combining the average life of options that have already been exercised and post-vest cancellations with the estimated life of the remaining vested and unexercised options. The expected volatility is based on the historical volatility

of the Company s stock. The risk-free interest rate is based on 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 per share was $6.72 and $3.40 for options granted during the nine months ended September 30, 2006 and 2005, respectively. The total intrinsic value was $3.2 million and $1.3 million for options exercised during the nine months ended September 30, 2006 and 2005, respectively. As of September 30, 2006, total unrecognized compensation cost related to stock options was approximately $3.4 million and the related weighted-average period over which it is expected to be recognized is approximately 2.1 years. The maximum contractual term of the Company s stock options is 10 years.

A summary of the status of stock option activity for the nine months ended September 30, 2006 is as follows (in thousands, except price and year 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	296	10.89		
Exercised	(449)	4.59		
Forfeited/expired	(36)	8.05		
Outstanding at September 30, 2006	2,264	$ 5.91	7.37	$ 16,967
Vested and expected to vest at September 30, 2006	2,115	$ 5.81	7.28	$ 16,048
Exercisable at September 30, 2006	1,210	$ 5.18	6.50	$ 9,948
Available for future grant at September 30, 2006	744			

The following table summarizes information about outstanding and exercisable options at September 30, 2006:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price of Options Exercisable
$2.25 - $3.38	182,416	5.09	$ 3.18	153,917	$ 3.18
$3.46 - $3.46	450,000	7.90	3.46	224,999	3.46
$3.54 - $3.99	256,159	7.18	3.81	122,156	3.86
$4.00 - $4.98	235,865	7.21	4.34	131,632	4.42
$5.00 - $5.70	277,411	6.09	5.47	273,036	5.47
$5.74 - $6.64	265,088	7.74	6.11	123,837	6.07
$6.71 - $9.36	242,812	7.57	8.06	96,405	7.37
$9.93 - $11.90	199,569	8.06	11.24	83,540	11.78
$12.23 - $12.23	147,000	9.49	12.23		
$13.09 - $13.09	8,000	9.21	13.09		
$2.25 - $13.09	2,264,320	7.37	$ 5.91	1,209,522	$ 5.18

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 vesting of a portion of the awards. A majority of stock awards granted in March 2006 were 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 the nine months ended September 30, 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	(197)	4.53
Forfeited		
Nonvested at September 30, 2006	628	$ 7.73

Stock-based compensation expense related to stock awards outstanding was approximately $0.4 million and $0.3 million during the three months ended September 30, 2006 and 2005, respectively, and approximately $1.1 million and $0.6 million during the nine months ended September 30, 2006 and 2005, 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

September 30, 2006 was approximately $4.1 million, which is expected to be recognized over a weighted-average period of approximately 2.5 years.

The pro forma impact to net earnings (loss) as if the fair value-based method had been applied to all stock options and stock awards for the three and nine months ended September 30, 2005 is as follows (in thousands, except per share amounts):

	Three months ended September 30, 2005	Nine months ended September 30, 2005
Net earnings (loss), as reported	$ 700	$ (18,861)
Add: Stock-based compensation expense included in reported net loss, net of related tax effects	347	591
Deduct: Stock-based compensation expense determined under fair value-based method for all awards, net of related tax effects	(656)	(1,611)
Pro forma net earnings (loss)	$ 391	$ (19,881)
Basic and diluted earnings (loss) per share as reported	$ 0.02	$ (0.58)
Basic and diluted earnings (loss) per share pro forma	$ 0.01	$ (0.61)

Note 9. Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48 (FIN 48) Accounting for Uncertainty in Income Taxes which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return, including a decision whether to file or not to file in a particular jurisdiction. Additionally, FIN 48 provides guidance on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. The accounting provisions of FIN 48 will be effective for the Company beginning January 1, 2007. The Company is in the process of determining the effect, if any, the adoption of FIN 48 will have on its consolidated financial position and results of operations.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. The provisions of SFAS 157 are effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact, if any, of the provisions of SFAS 157.

Note 10. Subsequent Events

In conjunction with previously disclosed communications between the Company and an industry participant, at the start of the fiscal fourth quarter, the Company entered into a sublicense agreement with a third party whereby the Company obtained a sublicense to certain lateral flow technology based on the terms of the agreement. Per the terms of the sublicense agreement, the Company made a one-time payment of $6.5 million to the third party during the fourth quarter of 2006 as consideration for the fully paid-up license, and the amount will be amortized ratably through the expiration of the applicable patents in December 2008.

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.

Forward-Looking Statements and 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, technological changes, the reimbursement system currently in place and future changes to that system, 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, required patent license fee payments not currently reflected in our costs, potential inadequacy of booked reserves, 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, anticipa estimate and similar words, although some forward-looking statements are 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 Securities and Exchange Commission (the SEC) from time to time should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management s analysis only as of the date of this 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 $66.3 million for the nine months ended September 30, 2006 from $54.6 million for the nine months ended September 30, 2005. This was largely driven by increased sales of our influenza and Group A Strep tests as we continued to focus our efforts to strengthen market and brand leadership in infectious disease and reproductive health by delivering economic and clinical proof through our efforts with our Quidel Value Build (QVB) program.

We derive a significant portion of our net sales from three product lines. For the nine months ended September 30, 2006 and 2005, we derived approximately 81% and 78%, respectively, of our net sales from sales of our influenza, pregnancy and Group A Strep tests. In the U.S., we lead the professional market in these three product categories with an estimated 72%, 49% and 48% market share in influenza, pregnancy and Group A Strep products, respectively, as of June 30, 2006. Additionally, we derive a significant portion of our net sales from a relatively small number of distributors. Approximately 74% and 71% of our net

sales for the nine months ended September 30, 2006 and 2005, respectively, were derived from sales through our five largest distributors in each of those periods.

Recent Developments

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

In conjunction with previously disclosed communications between the Company and an industry participant, at the start of the fiscal fourth quarter, the Company entered into a sublicense agreement with a third party whereby the Company obtained a sublicense to certain lateral flow technology based on the terms of the agreement. Per the terms of the sublicense agreement, the Company made a one-time payment of $6.5 million to the third party during the fourth quarter of 2006 as consideration for the fully paid-up license, and the amount will be amortized ratably through the expiration of the applicable patents in December 2008.

Outlook

For the remainder of 2006 and in looking forward to 2007, we anticipate continued year-over-year revenue growth, including revenue from new product launches. We believe gross margins will continue to be positively affected by increased sales volumes and a more favorable product and geographical mix and increased average selling prices, offset by increased strategic investments in our operational infrastructure and the annualized net impact, during 2006, 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 expect a gradual conversion of the fecal occult blood test market from the current guaiac-based test to an immunochemical based test. Successful conversion of this market requires changing physician behavior through education, focused on clinical and economic validation. Additionally, we expect our recently launched RSV product to be a well received companion test to our QuickVue Influenza A+B test so that physicians are well prepared to diagnose and appropriately manage patients with influenza and/or RSV. We anticipate continued investment spending in marketing and clinical trials in support of our new product launches and to further validate the clinical efficacy and economic efficiency of our existing products. We expect research and development expense to continue to increase as we expand our capabilities to accelerate innovation and invest in research and development of new technologies.

You should also refer to the discussion in Item 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 19% to $23.4 million for the three months ended September 30, 2006 from $19.7 million for the three months ended September 30, 2005 and increased 21% to $66.3 million for the nine months ended September 30, 2006 from $54.6 million for the nine months ended September 30, 2005. The increase for the three months ended September 30, 2006 was largely driven by an increase in sales of our influenza products of $3.9 million. The increase for the nine months ended September 30, 2006 was due to increased sales of our influenza and Group A Strep products of $8.0 million and $3.6 million, respectively. These two product lines accounted for 59% and 51% of our net sales for the nine months ended September 30, 2006 and September 30, 2005, respectively.

For both the three and nine months ended September 30, 2006, we believe revenue and market share related to these products has continued to increase due to successes related to our QVB programs, which have resulted in strengthened customer relationships and preferred partnership programs. The increase in our Group Strep A products was primarily related to the U.S. and Japanese markets, and driven by both increased volume and higher average selling prices. We believe that sales of our influenza products continue to increase as a result of increased market awareness and the demonstrated quality of our test. As of June 30, 2006, our U.S. professional market share is an estimated 48% and 72% for our Group A Strep and influenza products, respectively, and we are the market leader in both.

Research Contracts, License Fees and Royalty Income

Research contracts, license fees and royalty income remained constant at $0.3 million for the three months ended September 30, 2006 and 2005 and decreased to $0.9 million for the nine months ended September 30, 2006 from $2.9 million for the nine months ended September 30, 2005. The decrease for the nine months ended September 30, 2006 was primarily related to research contract revenue that we earned during the nine months ended September 30, 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 September 30, 2006 and 2005 relates to royalty payments received on a patented technology of ours utilized by third parties.

Cost of Sales and Gross Profit from Net Sales

Gross profit from net sales increased to $13.1 million for the three months ended September 30, 2006 from $10.4 million for the three months ended September 30, 2005 and increased to $36.8 million for the nine months ended September 30, 2006 from $30.3 million for the nine months ended September 30, 2005. Gross profit as a percentage of net sales increased to 56% for the three months ended September 30, 2006 from 53% for the three months ended September 30, 2005 and decreased to 55% for the nine months ended September 30, 2006 from 56% for the nine months ended September 30, 2005. For the three months ended September 30, 2006, the increase in gross profit as a percentage of sales was primarily due to increased volume, a more favorable product mix, and an increase in average selling prices, partially offset by increased strategic investment in our operational infrastructure. For the nine months ended September 30, 2006, the decrease in gross profit as a percentage of sales was primarily due to the 8.5% royalty we began paying on the majority of our products during the second quarter of 2005 related to the patent litigation settlement with Inverness Medical Innovations, Inc. (IMA), as discussed elsewhere in this report, and strategic investments in our operational infrastructure, partially offset by increased sales volume, a more favorable product mix and increased average selling price. In connection with the patent litigation settlement entered into during the second quarter of 2005, we are required, as of May 2005, to pay an 8.5% royalty on net sales of our current influenza, Group A Strep, pregnancy, H-Pylori, mononucleosis, chlamydia, iFOB and veterinary products. These product sales accounted for 93% and

88% of our net sales for the nine months ended September 30, 2006 and 2005, respectively. Royalty expense related to this settlement agreement was $1.9 million and $5.2 million for the three and nine months ended September 30, 2006, respectively. Also, for the nine months ended September 30, 2006, the gross profit as a percent of sales was favorably impacted compared to 2005 as we fulfilled the terms of an agreement with another party related to the development of our influenza product during the first quarter of 2005. We are no longer required to pay to this party a 6% royalty on sales of our influenza product. Our influenza products sales accounted for 34% and 27% of our net sales for the nine months ended September 30, 2006 and 2005, respectively.

Research and Development Expense

Research and development expense increased to $3.1 million for the three months ended September 30, 2006 from $3.0 million for the three months ended September 30, 2005 and increased to $9.9 million for the nine months ended September 30, 2006 from $9.3 million for the nine months ended September 30, 2005. Research and development expense as a percentage of net sales decreased to 13% of net sales for the three months ended September 30, 2006, as compared to 15% of net sales for the three months ended September 30, 2005 and decreased to 15% of net sales for the nine months ended September 30, 2006 from 17% of net sales for the nine months ended September 30, 2005. The primary components of this expense are personnel and material costs associated with development of potential new technologies and processes and with products under development. In addition, we continue to incur substantial costs related to clinical trials as well as our overall efforts under our QVB programs.

Sales and Marketing Expense

Sales and marketing expense increased to $4.1 million for the three months ended September 30, 2006 from $3.6 million for the three months ended September 30, 2005 and increased to $12.3 million for the nine months ended September 30, 2006 from $11.8 million for the nine months ended September 30, 2005. Sales and marketing expense as a percentage of net sales decreased to 17% of net sales for the three months ended September 30, 2006, as compared to 18% of net sales for the three months ended September 30, 2005 and decreased to 19% of net sales for the nine months ended September 30, 2006 from 22% of net sales for the nine months ended September 30, 2005. We continue to invest in assessment of future product extensions and enhancements, market research (including voice of customer surveys), programs aimed at distribution partners and end user customers, and reimbursement related activities.

General and Administrative Expense

General and administrative expense increased to $3.3 million for the three months ended September 30, 2006 from $2.5 million for the three months ended September 30, 2005 and decreased to $9.5 million for the nine months ended September 30, 2006 from $9.6 million for the nine months ended September 30, 2005. General and administrative expense as a percentage of net sales increased to 14% of net sales for the three months ended September 30, 2006 from 13% of net sales for the three months ended September 30, 2005 and decreased to 14% of net sales for the nine months ended September 30, 2006 from 18% of net sales for the nine months ended September 30, 2005. The absolute dollar increase for the three months ended September 30, 2006 was primarily due to $0.6 million in personnel related costs associated with stock-based compensation and management incentive plans. The absolute dollar decrease for the nine months ended September 30, 2006 was due primarily to decreased legal fees of $2.1 million associated with the settlement of our intellectual property litigation with IMA in the first quarter of 2005, offset by an increase in personnel related costs associated with stock-based compensation and management incentive plans of $2.0 million.

Patent Litigation Settlement

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

Amortization of Intangibles

On January 1, 2002, we adopted SFAS No. 141, Business Combinations, (SFAS No. 141) and SFAS No. 142, Goodwill and Other Intangible Assets, (SFAS 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 September 30, 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 $0.8 million for the three months ended September 30, 2006 from $0.3 million for the three months ended September 30, 2005 and increased to $3.0 million for the nine months ended September 30, 2006 from $0.9 million for the nine months ended September 30, 2005. The increase for the three and nine months ended September 30, 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 million and $0.2 million for the three months ended September 30, 2006 and 2005, respectively, and $1.1 million and $0.5 million for the nine months ended September 30, 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 September 30, 2006 and 2005 and $0.6 million for both the nine months ended September 30, 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 and nine months ended September 30, 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 we anticipate 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 $17.0 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 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 and nine months ended September 30, 2005.

Liquidity and Capital Resources

As of September 30, 2006, our principal source of liquidity consisted of $30.6 million in cash and cash equivalents. Our working capital as of September 30, 2006 was $42.8 million.

Our earnings from continuing operations provided cash of $8.9 million for the nine months ended September 30, 2006. We had net earnings of $3.4 million and $6.1 million of depreciation and amortization of intangible assets. The increase in inventories of $0.9 million for the nine months ended September 30, 2006 is due primarily to increased production during the three month period ending September 30, 2006 to meet increased demand. Other changes in operating assets and liabilities included a decrease in accounts receivable, accounts payable and accrued royalties of $0.5 million, $1.0 million and $1.2 million, respectively, due to the seasonal decrease in net sales for the period ended September 30, 2006 compared to the period ended December 31, 2005.

Our investing activities used $3.5 million during the nine months ended September 30, 2006, primarily driven by the acquisition of manufacturing equipment and building improvements.

Our financing activities used $9.7 million of cash during the nine months ended September 30, 2006 and were related primarily to the repurchase of $11.6 million of our common stock and $0.5 million for payments on obligations under our capital leases related to our building in San Diego. These items were partially offset by proceeds of $2.3 million from the issuance of common stock under our equity incentive plans.

We have approximately $2.0 million of firm purchase commitments with respect to the acquisition of our new iFOB test as of the date of filing this report. These commitments largely relate to inventory component purchases relating to our iFOB test. We are planning approximately $1.3 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.

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 September 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 September 30, 2006, we had $30.0 million of

availability under the Senior Secured Credit Facility and we believe 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 any such 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 September 30, 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 and director compensation plans under the measurement and recognition provisions of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations, as permitted by Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation. We recorded no share-based employee and director compensation expense for options granted under our 2001 Equity Incentive Plan or its predecessor plans prior to December 31, 2005, as all options granted under those plans had exercise prices equal to or greater than the fair market value of our common stock on the date of grant. We did not have material compensation expense in connection with our Employee Stock Purchase Plan. In accordance with SFAS 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 awards granted prior to, but not yet vested as of December 31, 2005, based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation expense for all share-based awards granted on or after January 1, 2006 based on the grant-date fair value estimated in accordance with the provisions of SFAS 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.

Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option award. The total number of stock options expected to vest is adjusted by estimated forfeiture rates. The estimated fair value of each stock option was determined on the date of grant using the Black-Scholes option valuation model. Compensation expense for restricted stock awards (stock awards) is measured at the grant date and recognized ratably over the vesting period. The fair value of stock awards is determined based on the closing market price of the Company s common stock on the grant date. For stock awards granted prior to December 31, 2005, vesting is based on both the service period as well as the achievement of Company performance goals. Meeting the performance goals for these awards allows for acceleration of a portion of the stock awards. A majority of the stock awards granted in March 2006 were performance based and vesting is tied to achievement of 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.

We record revenues from product sales. These revenues are recorded net of rebates and other discounts which are estimated at the time of sale. The rebates and other discounts are largely driven by various customer program offerings, including special pricing agreements, promotions and other volume-based incentives. Revenue from product sales is recorded upon passage of title and risk of loss to the customer. Change in title to the product and recognition of revenue occur upon delivery to the customer when sales terms are FOB destination and at the time of shipment when the sales terms are FOB shipping point. 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 as of December 31, 2005 and subsequently determined there were no impairment indicators as of September 30, 2006.

We did not recognize income tax expense for the nine months ended September 30, 2006 as the income tax provision for such period was offset by an income tax benefit from previously reserved deferred tax assets. We do not anticipate recording a tax provision during 2006 as we anticipate 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 September 30, 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 is 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 September 30, 2006. Based on our market risk sensitive instruments outstanding at September 30, 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 September 30, 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 September 30, 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 September 30, 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

Not applicable.

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 changes to the first two risk factors 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 nine months ended September 30, 2006, net sales increased 21% to $66.3 million from $54.6 million for the nine months September 30, 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, RSV 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 more clinically accurate or lower priced product to compete with one of our products;

- changes in the reimbursement systems or reimbursement amounts that end users rely upon in choosing to use our products;

- changes in economic conditions in our domestic and international markets, such as economic downturns, reduced consumer demand, inflation and currency fluctuations;

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

- lower than anticipated market penetration of our new products;

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

- changes in distributor buying patterns.

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.

On March 10, 2006, we 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.

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 and products and develop new markets could have a material adverse effect on our business and prospects.

We devote a significant amount of financial resources to researching and developing new technologies, new products and new markets. The development, manufacture and sale of diagnostic products require a significant investment of resources. Moreover, no assurances can be given that our efforts to develop new technologies or products will be successful, including, without limitation, our strategic efforts relating to: (i) our LTF technology platform and migration of select 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
- Pursue licensing, acquisition and partnership opportunities that meet our dedicated focus on Research to Rapids™.

As a result of any number of risk factors identified in this 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 many distributor relationships, the market is dominated by a small group of these distributors. Five of our distributors, which are considered to be among the market leaders, accounted for approximately 74% and 71% of our net sales for the nine months ended September 30, 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 June 30, 2006, our estimated U.S. professional market share for our key POC products was 72% for influenza, 49% for pregnancy and 48% 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 (and their affiliates), Beckman Coulter Primary Care Diagnostics, Fisher Scientific Corporation, Genzyme Diagnostics Corporation, and Becton Dickinson and Company. 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 several 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 19% and 22% of our net sales for the nine months ended September 30, 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 products, 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 8% increase in value of the Euro against the U.S. dollar for nine months ended September 30, 2006. We also have exposure to the Japanese Yen, which did not materially change in value against the U.S. dollar for the nine months ended September 30, 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 Marketplace 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 volatile and has fluctuated substantially in the past. For example, between September 30, 2005 and September 30, 2006, the price of our common stock, as reported on NASDAQ, has ranged from a low of $8.14 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 novel influenza viruses in human specimens;

- changes in the level of competition, such as would occur if one of our larger and better financed competitors introduced a new 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 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 September 30, 2006:

- approximately 33.3 million shares of our common stock had been issued in registered offerings and 32.7 million are freely tradable in the public markets, and 0.6 million relate to restricted shares; and

- approximately 2.3 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 $5.91.

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 September 30, 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 July 1, 2006	355,500	$ 8.84	355,500	$ 21,800,000
July 1 July 30, 2006	706,259	9.44	706,259	15,100,000
August 1 August 31, 2006	190,243	9.00	190,243	13,400,000
September 1 September 30, 2006				13,400,000
Ending balance September 30, 2006	1,252,002	$ 9.20	1,252,002	$ 13,400,000

(1) In September 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 May 19, 2007 unless extended by our Board of Directors.

In addition to the stock repurchase program noted above 394 shares of common stock, at a cost of $9.94 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 September 30, 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.)
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.

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: November 3, 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)

Exhibit Index

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