

INVERNESS MEDICAL INNOVATIONS INC

Form 10-Q

May 10, 2007

Table of Contents

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2007

OR

**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 001-16789
INVERNESS MEDICAL INNOVATIONS, INC.
(Exact Name Of Registrant As Specified In Its Charter)**

DELAWARE

(State or other jurisdiction of
incorporation or organization)

04-3565120

(I.R.S. Employer
Identification No.)

**51 SAWYER ROAD, SUITE 200
WALTHAM, MASSACHUSETTS 02453**

(Address of principal executive offices)

(781) 647-3900

(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 No

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. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

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

Yes No

The number of shares outstanding of the registrant's common stock, par value of \$0.001 per share, as of May 4, 2007 was 46,584,855.

INVERNESS MEDICAL INNOVATIONS, INC.
REPORT ON FORM 10-Q
For the Quarterly Period Ended March 31, 2007

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, estimate, continue or similar words. There are a number of important factors that could cause actual results of Inverness Medical Innovations, Inc. and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the risk factors detailed in Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K for the fiscal year ending December 31, 2006, as amended and other risk factors identified herein or from time to time in our periodic filings with the Securities and Exchange Commission. Readers should carefully review these factors as well as the Special Statement Regarding Forward-Looking Statements beginning on page 35, in this Quarterly Report on Form 10-Q and should not place undue reliance on our forward-looking statements. These forward-looking statements are based on information, plans and estimates at the date of this report. We undertake no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to we, us and our refer to Inverness Medical Innovations, Inc. and its subsidiaries.

TABLE OF CONTENTS

| | PAGE |
|--|-------------|
| <u>PART I. FINANCIAL INFORMATION</u> | |
| <u>Item 1. Financial Statements (unaudited):</u> | |
| <u>a) Consolidated Statements of Operations for the three months ended March 31, 2007 and 2006</u> | 3 |
| <u>b) Consolidated Balance Sheets as of March 31, 2007 and December 31, 2006</u> | 4 |
| <u>c) Consolidated Statements of Cash Flows for the three months ended March 31, 2007 and 2006</u> | 5 |
| <u>d) Notes to Consolidated Financial Statements</u> | 6 |
| <u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 25 |
| <u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u> | 36 |
| <u>Item 4. Controls and Procedures</u> | 37 |
| <u>PART II. OTHER INFORMATION</u> | |
| <u>Item 1A. Risk Factors</u> | 37 |
| <u>Item 6. Exhibits</u> | 37 |
| <u>SIGNATURE</u> | 39 |
| <u>EX-4.1 Sixth Supplemental Indenture, dated as of March 14, 2007</u> | |
| <u>EX-4.2 Seventh Supplemental Indenture, dated as of May 1, 2007</u> | |

EX-31.1 Section 302 Certification of CEO

EX-31.2 Section 302 Certification of CFO

EX-32.1 Section 906 Certification of CEO & CFO

Table of Contents**PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS**

(unaudited)

(in thousands, except per share amounts)

| | Three Months Ended March | |
|--|---------------------------------|-------------------|
| | 31, | |
| | 2007 | 2006 |
| Net product sales | \$ 153,749 | \$ 122,753 |
| License and royalty revenue | 5,230 | 5,068 |
| Net revenue | 158,979 | 127,821 |
| Cost of sales | 80,641 | 75,567 |
| Gross profit | 78,338 | 52,254 |
| Operating expenses: | | |
| Research and development (Note 11) | 12,009 | 10,610 |
| Sales and marketing | 28,331 | 20,822 |
| General and administrative | 22,659 | 15,838 |
| Total operating expenses | 62,999 | 47,270 |
| Operating income | 15,339 | 4,984 |
| Interest expense, including amortization of original issue discounts and write-off of deferred financing costs (Note 13) | (5,184) | (5,721) |
| Other income (expense), net | 2,029 | (428) |
| Income (loss) before provision for income taxes | 12,184 | (1,165) |
| Provision for income taxes | 5,879 | 1,465 |
| Net income (loss) | \$ 6,305 | \$ (2,630) |
| Net income (loss) per common share basic (Note 5) | \$ 0.14 | \$ (0.09) |
| Net income (loss) per common share diluted (Note 5) | \$ 0.14 | \$ (0.09) |
| Weighted average common shares basic (Note 5) | 44,446 | 29,585 |
| Weighted average common shares diluted (Note 5) | 46,198 | 29,585 |

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS**

(unaudited)

(in thousands, except par value)

| | March 31, 2007 | December 31, 2006 |
|--|---------------------------|----------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 180,941 | \$ 71,104 |
| Accounts receivable, net of allowances of \$8,870 at March 31, 2007 and \$8,401 at December 31, 2006 | 99,876 | 100,388 |
| Inventories, net | 87,331 | 78,322 |
| Deferred tax assets | 5,416 | 5,332 |
| Related party note receivable | 14,733 | |
| Prepaid expenses and other current assets | 21,923 | 20,398 |
| Total current assets | 410,220 | 275,544 |
| Property, plant and equipment, net | 81,330 | 82,312 |
| Goodwill | 489,435 | 439,369 |
| Other intangible assets with indefinite lives | 68,402 | 68,107 |
| Core technology and patents, net | 87,565 | 87,732 |
| Other intangible assets, net | 105,369 | 83,794 |
| Deferred financing costs, net and other non-current assets | 13,101 | 13,218 |
| Other investments and available-for-sale securities | 83,914 | 35,617 |
| Deferred tax assets | 1,038 | 78 |
| Total assets | \$ 1,340,374 | \$ 1,085,771 |
| LIABILITIES AND STOCKHOLDERS EQUITY | | |
| Current liabilities: | | |
| Current portion of long-term debt | \$ 8,876 | \$ 7,504 |
| Current portion of capital lease obligations | 597 | 584 |
| Accounts payable | 42,898 | 46,342 |
| Accrued expenses and other current liabilities | 70,701 | 87,801 |
| Total current liabilities | 123,072 | 142,231 |
| Long-term liabilities: | | |
| Long-term debt, net of current portion | 150,132 | 194,473 |
| Capital lease obligations, net of current portion | 259 | 415 |
| Deferred tax liabilities | 28,588 | 23,984 |
| Other long-term liabilities | 11,644 | 10,530 |
| Total long-term liabilities | 190,623 | 229,402 |

Commitments and contingencies (Note 17)**Series A redeemable convertible preferred stock, \$0.001 par value:**

Authorized: 2,667 shares

Issued: 2,527 shares at March 31, 2007 and December 31, 2006

Outstanding: none at March 31, 2007 and December 31, 2006

Stockholders equity:

Preferred stock, \$0.001 par value

Authorized: 2,333 shares

Issued: none

Common stock, \$0.001 par value

Authorized: 100,000 shares

Issued and outstanding: 46,573 shares at March 31, 2007 and 39,215 shares at

December 31, 2006

Additional paid-in capital

Accumulated deficit

Accumulated other comprehensive income

Total stockholders equity**Total liabilities and stockholders equity**

| | | |
|--|--------------|--------------|
| | 47 | 39 |
| | 1,105,837 | 826,987 |
| | (120,764) | (127,069) |
| | 41,559 | 14,181 |
| | 1,026,679 | 714,138 |
| | \$ 1,340,374 | \$ 1,085,771 |

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)
(in thousands)

| | Three Months Ended March | |
|---|---------------------------------|-----------------|
| | 31, | |
| | 2007 | 2006 |
| Cash Flows from Operating Activities: | | |
| Net income (loss) | \$ 6,305 | \$ (2,630) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | |
| Interest expense related to amortization and write-off of non-cash original issue discount and deferred financing costs | 1,139 | 677 |
| Non-cash income related to currency hedge | | (217) |
| Non-cash stock-based compensation expense | 1,593 | 1,318 |
| Loss on sale of fixed assets | 50 | |
| Interest in minority investments | (436) | |
| Depreciation and amortization | 11,129 | 7,646 |
| Deferred and other non-cash income taxes | 3,796 | 743 |
| Other non-cash items | 96 | 141 |
| Changes in assets and liabilities, net of acquisitions: | | |
| Accounts receivable, net | 9,484 | (6,308) |
| Inventories, net | (3,195) | 4,413 |
| Prepaid expenses and other current assets | (1,418) | (780) |
| Accounts payable | (8,067) | (7,367) |
| Accrued expenses and other current liabilities | (13,874) | (4,469) |
| Other non-current liabilities | 938 | 91 |
| Net cash provided by (used in) operating activities | 7,540 | (6,742) |
| Cash Flows from Investing Activities: | | |
| Purchases of property, plant and equipment | (3,075) | (4,349) |
| Proceeds from sale of equipment | 38 | 33 |
| Note receivable with related party | (14,733) | |
| Cash paid for acquisitions and transactional costs, net of cash acquired | (68,160) | (70,169) |
| Cash paid for minority interest investments and available-for-sale securities | (25,602) | |
| (Increase) decrease in other assets | (1,877) | 1,040 |
| Net cash used in investing activities | (113,409) | (73,445) |
| Cash Flows from Financing Activities: | | |
| Cash paid for financing costs | (137) | (316) |
| Proceeds from issuance of common stock, net of issuance costs | 264,132 | 82,128 |
| Net proceeds (payments) under revolving line of credit | 68 | (3,654) |
| Tax benefit on exercised stock options | 160 | |
| Repayments of notes payable | (49,700) | (42) |
| Principal payments of capital lease obligations | (143) | (137) |

| | | |
|---|------------|-----------|
| Net cash provided by financing activities | 214,380 | 77,979 |
| Foreign exchange effect on cash and cash equivalents | 1,326 | 1,463 |
| Net increase (decrease) in cash and cash equivalents | 109,837 | (745) |
| Cash and cash equivalents, beginning of period | 71,104 | 34,270 |
| Cash and cash equivalents, end of period | \$ 180,941 | \$ 33,525 |
| Supplemental Disclosure of Non-cash Activities: | | |
| Fair value of stock issued for acquisitions | \$ 13,133 | \$ 25,480 |

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(unaudited)

(1) Basis of Presentation of Financial Information

The accompanying consolidated financial statements of Inverness Medical Innovations, Inc. and its subsidiaries are unaudited. In the opinion of management, the unaudited consolidated financial statements contain all adjustments considered normal and recurring and necessary for their fair presentation. Interim results are not necessarily indicative of results to be expected for the year. These interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these consolidated financial statements do not include all of the information and footnotes necessary for a complete presentation of financial position, results of operations and cash flows. Our audited consolidated financial statements for the year ended December 31, 2006 included information and footnotes necessary for such presentation and were included in our Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on March 26, 2007. These unaudited consolidated financial statements should be read in conjunction with our audited consolidated financial statements and notes thereto for the year ended December 31, 2006.

(2) Cash and Cash Equivalents

We consider all highly liquid cash investments with original maturities of three months or less at the date of acquisition to be cash equivalents. At March 31, 2007, our cash equivalents consisted of money market funds.

(3) Inventories

Inventories are stated at the lower of cost (first in, first out) or market and are comprised of the following (in thousands):

| | March 31, 2007 | December 31, 2006 |
|-----------------|---------------------------|------------------------------|
| Raw materials | \$ 26,673 | \$ 29,372 |
| Work-in-process | 20,883 | 19,080 |
| Finished goods | 39,775 | 29,870 |
| | \$ 87,331 | \$ 78,322 |

(4) Stock-Based Compensation

Effective January 1, 2006, we began recording compensation expense associated with stock options and other forms of equity compensation in accordance with Statement of Financial Accounting Standards (SFAS) No. 123-R, *Share-Based Payment*, as interpreted by SEC Staff Accounting Bulletin No. 107. Prior to January 1, 2006, we accounted for stock options according to the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, and therefore no related compensation expense was recorded for awards granted with no intrinsic value. We adopted the modified prospective transition method provided for under SFAS No. 123-R, and consequently have not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options now includes: (i) amortization 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 (ii) amortization 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 123-R. In addition, we record expense over the offering period in connection with shares issued under our employee stock purchase plan. The compensation expense for stock-based compensation awards includes an estimate for forfeitures and is recognized over the expected term of the options using the straight-line method.

In accordance with SFAS No. 123-R, as of March 31, 2007, our results of operations reflected compensation expense for new stock options granted and vested under our stock incentive plan and employee stock purchase plan

during the first three months of 2007 and 2006 and the unvested portion of previous stock option grants which vested during the first three months of 2007 and 2006. Stock-based compensation expense in the amount of \$1.6 million (\$1.4 million, net of tax) and \$1.3 million (\$1.2 million, net of tax) was reflected in the consolidated statement of operations for the first three months of 2007 and 2006, respectively, as follows (in thousands):

6

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS **Continued**
(unaudited)

| | Three Months Ended March | |
|----------------------------|---------------------------------|-----------------|
| | 31, | |
| | 2007 | 2006 |
| Cost of sales | \$ 85 | \$ 109 |
| Research and development | 223 | 270 |
| Sales and marketing | 324 | 188 |
| General and administrative | 961 | 751 |
| | \$ 1,593 | \$ 1,318 |

In accordance with SFAS No. 123-R, we report the excess tax benefits from the exercise of stock options as financing cash flows. For the three months ended March 31, 2007 and 2006, there was \$0.2 million and \$0, respectively, of excess tax benefits generated from option exercises.

Our stock option plans provide for grants of options to employees to purchase common stock at the fair market value of such shares on the grant date of the award. The options vest over a four year period, beginning on the date of grant, with a graded vesting schedule of 25% at the end of each of the four years. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing method. We use historical data to estimate the expected price volatility and the expected forfeiture rate. For the three months ended March 31, 2007 and 2006, we have chosen to employ the simplified method of calculating the expected option term, which averages an award's weighted average vesting period and its contractual term. The contractual term of our stock option awards is ten years. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant with a remaining term equal to the expected term of the option. We have not made any dividend payments nor do we have plans to pay dividends in the foreseeable future. The following assumptions were used to estimate the fair value of options granted during the first three months of 2007 and 2006 using the Black-Scholes option-pricing model:

| | Three Months Ended March | |
|-------------------------|---------------------------------|-------------|
| | 31, | |
| | 2007 | 2006 |
| Stock Options: | | |
| Risk-free interest rate | 4.53% | 4.38% |
| Expected dividend yield | | |
| Expected term | 6.25 years | 6.25 years |
| Expected volatility | 44.69% | 42% |

| | Three Months Ended March | |
|--------------------------------------|---------------------------------|-------------|
| | 31, | |
| | 2007 | 2006 |
| Employee Stock Purchase Plan: | | |
| Risk-free interest rate | 4.94% | 4.55% |
| Expected dividend yield | | |
| Expected term | 181 days | 181 days |
| Expected volatility | 32.64% | 32.71% |

A summary of the stock option activity for the three months ended March 31, 2007 is as follows (in thousands, except price per share and contractual term):

**Weighted
Average**

| | Options | Weighted Average Exercise Price | Remaining Contractual Term | Aggregate Intrinsic value |
|--------------------------------------|----------------|--|---|--|
| Options outstanding, January 1, 2007 | 3,775 | \$ 21.11 | | |
| Granted | 218 | \$ 40.79 | | |
| Exercised | (111) | \$ 19.32 | | |
| Canceled/forfeited/expired | (4) | \$ 54.74 | | |
| Options outstanding, March 31, 2007 | 3,878 | \$ 22.23 | 6.5 years | \$ 83,765 |
| Options exercisable, March 31, 2007 | 2,403 | \$ 17.11 | 5.1 years | \$ 64,297 |

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during the three months ended March 31, 2007 and 2006 was \$20.54 per share and \$12.89 per share, respectively.

7

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
(unaudited)

As of March 31, 2007, there was \$15.9 million, net of estimated forfeitures, related to unvested stock options that are expected to vest. That cost is expected to be recognized over a weighted-average period of 2.77 years.

(5) Net Income (Loss) Per Common Share

The following table sets forth the computation of basic and diluted net income (loss) per common share (in thousands, except per share amounts):

| | Three Months Ended March | |
|--|---------------------------------|-------------|
| | 2007 | 2006 |
| Numerator: | | |
| Net income (loss) basic and diluted | \$ 6,305 | \$ (2,630) |
| Denominator: | | |
| Denominator for basic net income (loss) per common share weighted average shares | 44,446 | 29,585 |
| Effect of dilutive securities: | | |
| Stock options | 1,567 | |
| Warrants | 185 | |
| Dilutive potential common shares | 1,752 | |
| Denominator for diluted net income (loss) per common share weighted average shares | 46,198 | 29,585 |
| Net income (loss) per common share basic | \$ 0.14 | \$ (0.09) |
| Net income (loss) per common share diluted | \$ 0.14 | \$ (0.09) |

We had the following potential dilutive securities outstanding on March 31, 2007: options to purchase an aggregate of 0.7 million shares of common stock. These potential dilutive securities were not included in the computation of diluted net income (loss) per common share because the effect of including such potential dilutive securities would be anti-dilutive.

We had the following potential dilutive securities outstanding on March 31, 2006: (a) options and warrants to purchase an aggregate of 4.4 million shares of common stock at a weighted average exercise price of \$18.71 per share, and (b) 104,000 shares of common stock held in escrow. These potential dilutive securities were not included in the computation of diluted net income (loss) per common share because the effect of including such potential dilutive securities would be anti-dilutive.

(6) Uncertain Income Tax Positions

We adopted Financial Accounting Standards Board (FASB) Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement 109* on January 1, 2007. The cumulative effect of adopting FIN 48 had no change to the January 1, 2007 retained earnings balance. Upon adoption, the liability for income taxes associated with uncertain tax positions at January 1, 2007 was \$2.2 million. This amount of \$2.2 million, if recognized, would favorably affect our effective tax rate. In addition, consistent with the provisions of FIN 48, we

classified \$2.2 million of income tax liabilities as non-current income tax liabilities because a payment of cash is not anticipated within one year of balance sheet date. In the three months period ending March 31, 2007, we increased the liability for income taxes associated with uncertain tax positions by \$0.2 million for a total of \$2.4 million at March 31, 2007. These non-current income tax liabilities are recorded in other long-term liabilities in our consolidated balance sheet at March 31, 2007.

Interest and penalties related to income tax liabilities are included in income tax expense. The balance of accrued interest and penalties recorded in the consolidated balance sheet at January 1, 2007 was \$ 0.1 million. In the three months period ending March 31, 2007, we accrued an additional amount of approximately \$20,000 for interest and penalties for a total of \$0.1 million at March 31, 2007.

With limited exception, we are subject to U.S. federal, state and local or non-U.S. income tax audits by tax authorities for all years. We are currently under income tax examination by a number of state and foreign tax authorities and anticipate these audits will be completed by the end of 2008. We do anticipate an increase every quarter to the total amount of unrecognized tax benefits.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
(unaudited)

(7) Comprehensive Income or Loss

We account for comprehensive income as prescribed by SFAS No. 130, *Reporting Comprehensive Income*. In general, comprehensive income (loss) combines net income (loss) and other changes in equity during the year from non-owner sources. Our accumulated other comprehensive income, which is a component of shareholders' equity, includes primarily foreign currency translation adjustments and is our only source of equity from non-owners. For the three months ended March 31, 2007 and 2006, we generated a comprehensive gain of \$33.7 million and \$0.5 million, respectively.

(8) Stockholders' Equity

We raised net proceeds of approximately \$261.3 million through an underwritten public offering of 6,900,000 shares of our common stock. In January 2007, we sold 6,000,000 shares to the public at \$39.65 per share, and in February 2007, our underwriters exercised in full an option to purchase an additional 900,000 shares to cover over-allotments. Net proceeds include deductions for underwriting discounts and commissions and take into effect the reimbursement by the underwriters of a portion of our offering expenses. Of this amount, we used \$44.9 million to repay principal outstanding and accrued interest on our term loan under our senior credit facility, with the remainder of the net proceeds retained for working capital and other general corporate purposes, including the financing of potential acquisitions or other investments.

(9) Business Combinations

Acquisitions are an important part of our growth strategy. When we acquire businesses, we seek to complement existing products and services, enhance or expand our product lines and/or expand our customer base. We determine what we are willing to pay for each acquisition partially based on our expectation that we can cost effectively integrate the products and services of the acquired companies into our existing infrastructure. In addition, we utilize existing infrastructure of the acquired companies to cost effectively introduce our products to new geographic areas.

We account for our acquisitions using the purchase method of accounting as defined under SFAS No. 141, *Business Combinations*. Accordingly, the operating results of the acquired company is included in our consolidated financial statements of operations after the acquisition date as part of reporting unit it relates to. Accounting for these acquisitions has resulted in the capitalization of the cost in excess of fair value of the net assets acquired in each of these acquisitions as goodwill. We estimated the fair values of the assets acquired in each acquisition as of the date of acquisition and these estimates are subject to adjustment. We complete these assessments within one year of the date of acquisition. We have undertaken certain restructurings of the acquired businesses to realize efficiencies and potential cost savings. Our restructuring activities include the elimination of duplicate facilities, reductions in staffing levels, and other costs associated with exiting certain activities of the businesses we acquire. The estimated cost of these restructuring activities are included as costs of the acquisition and are recorded as additional purchase price consistent with the guidance of Emerging Issue Task Force (EITF) Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination*. Any common stock issued with our acquisitions is determined based on the average market price of our common stock pursuant to Issue No. 99-12, *Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination*.

(a) Acquisition of Instant Technologies, Inc.

On March 12, 2007, we acquired 75% of the issued and outstanding capital stock of Instant Technologies, Inc. (Instant), a privately-owned distributor of rapid drugs of abuse diagnostic products used in the workplace, criminal justice and other testing markets. The preliminary aggregate purchase price was \$43.9 million, which consisted of \$30.6 million in cash, 0.3 million shares of our common stock with an aggregate fair value of \$13.1 million and \$0.2 million in direct acquisition costs.

The aggregate purchase price was preliminarily allocated to the assets acquired and liabilities assumed at the date of acquisition as follows (in thousands):

| | |
|---------------------------|--------|
| Cash and cash equivalents | \$ 327 |
|---------------------------|--------|

Edgar Filing: INVERNESS MEDICAL INNOVATIONS INC - Form 10-Q

| | |
|---------------------------------------|-----------|
| Accounts receivable | 3,638 |
| Inventories | 4,448 |
| Other assets | 780 |
| Property, plant and equipment | 141 |
| Goodwill | 36,306 |
| Trademarks | 2,500 |
| Customer relationships | 10,000 |
| Accounts payable and accrued expenses | (4,279) |
| Long-term debt | (4,925) |
| Deferred tax liability | (5,000) |
| | \$ 43,936 |

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS **Continued**
(unaudited)

The above values for the assets acquired and liabilities assumed are based on preliminary management estimates due to the timing of the acquisition. Final purchase price allocation may differ from the above. Management has assigned an estimated useful life of 10 years to trademarks and customer relationships and has recorded both assets in other intangibles, net in the accompanying consolidated balance sheet.

The operating results of Instant are included in our professional diagnostic products reporting unit and business segment.

(b) Acquisition of First Check Diagnostics LLC

On January 31, 2007, we acquired substantially all of the assets of First Check Diagnostics LLC (First Check), a privately-held diagnostics company in the field of home testing for drugs of abuse, including marijuana, cocaine, methamphetamines and opiates. The preliminary aggregate purchase price was approximately \$24.7 million, which consisted of \$24.5 million in cash and \$0.2 million in direct acquisition costs.

The aggregate purchase price was preliminarily allocated to the assets acquired and liabilities assumed at the date of acquisition as follows (in thousands):

| | |
|---------------------------------------|------------------|
| Accounts receivable | \$ 1,569 |
| Inventories | 638 |
| Other assets | 40 |
| Property, plant and equipment | 7 |
| Goodwill | 11,370 |
| Trademarks | 1,300 |
| Customer relationships | 11,000 |
| Accounts payable and accrued expenses | (1,184) |
| | \$ 24,740 |

The above values for the assets acquired and liabilities assumed are based on preliminary management estimates due to the timing of the acquisition. Final purchase price allocation may differ from the above. Management has assigned an estimated useful life of 10 years to trademarks and customer relationships and has recorded both assets in other intangibles, net in the accompanying consolidated balance sheet.

The operating results of First Check are included in our consumer products reporting unit and business segment. Goodwill generated from this acquisition is not deductible for tax purposes.

(c) Various Other Acquisitions

During the first quarter of 2007, we acquired the following businesses for a preliminary aggregate purchase price of \$6.7 million, which was paid in cash:

Promesan S.r.l. (Promesan), located in Milan, Italy, a distributor of point-of-care diagnostic testing products to the Italian marketplace

the assets of Nihon Schering K.K. (NSKK), located in Japan, a diagnostic distribution business

Gabmed, located in Nettetal, Germany, a distributor of point-of care diagnostic testing products in the German marketplace

NSKK is included in our consumer and professional diagnostic products reporting unit and business segment and Gabmed and Promesan are included in our professional diagnostic products reporting unit and business segment. Goodwill has been preliminarily recognized in the Gabmed and Promesan transactions and amounted to approximately \$4.8 million. Preliminary valuations of intangible assets have been performed for these acquisitions; however adjustments to intangible assets, and the resulting goodwill, may occur as final valuations are prepared.

Goodwill related to the Promesan and Gabmed acquisitions is not deductible for tax purposes. Goodwill related to the NSKK acquisition is expected to be fully deductible for tax purposes.

(d) Restructuring Plans of Acquisitions

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS **Continued**
(unaudited)

In connection with our acquisitions of Thermo BioStar, Inc. (BioStar), Ischemia Technologies, Inc. (Ischemia), Ostex International, Inc. (Ostex), IVC Industries, Inc. (now operating as Inverness Medical Nutritionals Group or IMN) and certain entities, businesses and intellectual property of Unilever Plc (the Unipath business), we recorded restructuring costs as part of the respective aggregate purchase prices in accordance with EITF No. 95-3.

The following table sets forth the restructuring costs recorded to date in connection with the restructuring activities of these acquired businesses (in thousands):

| | Total | Severance Related | Impairment of Fixed Assets | Facility Related |
|----------------------------------|-----------------|------------------------------|---|-----------------------------|
| BioStar | \$ 521 | \$ 83 | \$ 438 | \$ |
| Ischemia | 1,725 | 1,590 | | 135 |
| Ostex | 3,941 | 2,081 | | 1,860 |
| IMN | 1,587 | 1,587 | | |
| Unipath business | 4,159 | 4,159 | | |
| Total restructuring costs | \$11,933 | \$9,500 | \$ 438 | \$1,995 |

All restructuring charges related to these plans have been accounted for as of March 31, 2007. The total number of employees to be involuntarily terminated under these plans was 176, of which all have been terminated as of March 31, 2007. As of March 31, 2007, \$1.6 million related to severance charges and \$0.6 million related to facility exit costs remain unpaid.

(e) Pro Forma Financial Information

The following table presents selected unaudited financial information of our company, including the assets of ACON laboratories business of researching, developing, manufacturing, marketing and selling lateral flow immunoassay and directly-related products in the United States, Canada, Europe (excluding Russia, the former Soviet Republics that are not part of the European Union and Turkey), Israel, Australia, Japan and New Zealand (the Innovacon business) including ABON BioPharm (Hangzhou) Co., Ltd (ABON), the owner of a newly-constructed manufacturing facility in Hangzhou, China and Instant, as if the acquisitions of these entities had occurred on January 1, 2006. Pro forma results exclude adjustments for various other less significant acquisitions completed since January 1, 2006, as these acquisitions did not materially affect our results of operations. The pro forma results are derived from the historical financial results of the acquired businesses for all periods presented and are not necessarily indicative of the results that would have occurred had the acquisitions been consummated on January 1, 2006.

| | Three Months Ended March 31, | |
|--|---|-------------|
| | 2007 | 2006 |
| | (in thousands, except per share amounts) | |
| Pro forma net revenue | \$ 163,816 | \$ 144,668 |
| Pro forma net income | \$ 6,632 | \$ 26 |
| Pro forma net income per common share basic (1) | \$ 0.15 | \$ 0.00 |
| Pro forma net income per common share diluted (1) | \$ 0.14 | \$ 0.00 |

(1) Net income per common share amounts are computed as described in Note 5.

(10) Restructuring Plans

In May 2006, we committed to a plan to cease operations at our manufacturing facility in San Diego, California and to write off certain excess manufacturing equipment at other impacted facilities. Additionally, in June 2006, we committed to a plan to reorganize the sales and marketing and customer service functions in certain of our U.S. professional diagnostic companies. During the three months ended March 31, 2007, we recorded \$0.5 million in restructuring charge under these plans. The \$0.5 million included \$0.1 million related to severance charges and \$0.4 million related to facility exit costs. The \$0.5 million was charged to general and administrative expense and was included in our professional diagnostic products business segments. Including the charges recorded through March 31, 2007, we have incurred total restructuring charges related to these plans of approximately \$12.6 million. Substantially, all severance related charges have been expensed. The total number of employees to be involuntarily terminated under these plans is 132, of which 129 have been terminated as of March 31, 2007. As of March 31, 2007, \$0.2 million related to severance charges remain unpaid.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS **Continued**
(unaudited)

(11) Other Arrangements

On February 25, 2005, we entered into a co-development agreement with ITI Scotland Limited (ITI), whereby ITI agreed to provide us with approximately £30 million over three years to partially fund research and development programs focused on identifying novel biomarkers and near-patient and home use tests for cardiovascular and other diseases (the Programs). We agreed to invest £37.5 million in the Programs over three years from the date of the agreement. Through our subsidiary, Stirling Medical Innovations Limited (Stirling), we established a new research center in Stirling, Scotland, where we consolidated many of our existing cardiology programs and will ultimately commercialize products arising from the Programs. ITI and Stirling will have exclusive rights to the developed technology in their respective fields of use. As of March 31, 2007, we had received approximately \$40.9 million in funding from ITI. As qualified expenditures are made under the co-development arrangement, we recognize the fee earned during the period as a reduction of our related expenses, subject to certain limitations. For the three months ended March 31, 2007 and 2006, we recognized \$4.9 million and \$4.3 million of reimbursements, respectively, of which \$4.4 million and \$3.8 million, respectively, offset our research and development spending and \$0.5 million in both periods reduced our general, administrative and marketing spending incurred by Stirling.

(12) Other Investments and Available-for-sale Securities*(a) Investment in Chembio Diagnostics, Inc.*

In September 2006, we acquired 5% of Chembio Diagnostics, Inc. (Chembio), a developer and manufacturer of rapid diagnostic tests for infectious diseases, through the purchase of 40 shares of their preferred stock. The preferred stock pays a dividend of 7%, payable in cash or common stock. The aggregate purchase price of \$2.0 million was paid in cash. In addition to the preferred stock, we received a warrant to purchase 625,000 shares of Chembio's common stock at \$0.80 per share. Chembio's stock is publicly traded. The warrant, accounted for as a derivative instrument, had a fair value of approximately \$0.4 million at the date of issuance. The fair value of this warrant was estimated at the time of issuance using the Black-Scholes pricing model and assuming no dividend yield, expected volatility of 116%, risk-free rate of 4.9% and a contractual term of five years. We mark to market the warrant over the contractual term. As of March 31, 2007 and December 31, 2006, the warrant was valued at \$0.3 million and \$0.4 million, respectively.

(b) Equity Method Investments

In November 2006, we acquired 40% of Vedalab S.A. (Vedalab), a French manufacturer and supplier of rapid diagnostic tests in the professional markets. The aggregate purchase price was \$9.7 million which consisted of \$7.6 million in cash, 49,787 shares of our common stock with an aggregate fair value of \$2.0 million and \$0.1 million in estimated direct acquisition costs. On the same date, we settled an ongoing patent infringement claim with Vedalab. Under the terms of the settlement, Vedalab paid to us \$5.1 million and agreed to pay royalties on future sales ranging from 5% to 10%, depending on the products being sold in exchange for a license under certain patents to manufacture its current products as its facility in Alencon, France. In January, 2007, we received \$0.7 million from Vedalab in the form of a dividend distribution. This was accounted for as a reduction in the value of our investment in accordance with APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*. We account for our 40% investment in Vedalab under the equity method of accounting in accordance with APB Opinion No. 18. For the three months ended March 31, 2007, we recorded \$0.1 million in other income, which represented our minority share of Vedalab's profit for the respective period.

In May 2006, we acquired 49% of TechLab, Inc. (TechLab), a privately-held developer, manufacturer and distributor of rapid non-invasive intestinal diagnostics tests in the areas of intestinal inflammation, antibiotic associated diarrhea and parasitology. The aggregate purchase price was \$8.8 million which consisted of 303,417 shares of our common stock with an aggregate fair value of \$8.6 million and \$0.2 million in estimated direct acquisition costs. We account for our 49% investment in TechLab under the equity method of accounting, in accordance with APB Opinion No. 18. For the three months ended March 31, 2007, we recorded \$0.3 million in other income, which represented our minority share of TechLab's profit for the respective period.

(c) Available-for-sale Securities

Our investment in available-for-sale securities (long-term) consists of 750,000 shares of common stock in Biosite purchased since December 2006. We intend to hold these securities indefinitely and therefore have classified them as long-term in our accompanying consolidated balance sheet. Upon purchase, the shares were recorded at their market value, as measured by their closing price on the Nasdaq Capital Market. Unrealized holding gains and losses on available-for-sale securities are reported in accumulated other comprehensive income within stockholders' equity. As of March 31, 2007, the fair value of these securities was approximately \$63.0 million, which included unrealized holding gains of approximately \$24.0 million for the three months ended March 31, 2007.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
(unaudited)

(13) Senior Credit Facilities

As of December 31, 2006, \$44.8 million of borrowings were outstanding under our senior credit facility. On February 1, 2007, using a portion of the proceeds from our sale of 6.9 million shares of common stock in the first quarter of 2007 (Note 8), we paid the remaining principal balance outstanding and accrued interest under our senior credit facility.

Borrowings under the revolving lines of credit bear interest at either (i) the London Interbank Offered Rate (LIBOR), as defined in the agreement, plus applicable margins or, at our option or (ii) a floating Index Rate, as defined in the agreement, plus applicable margins. Applicable margins, if we choose to use the LIBOR or the Index Rate, can range from 2.75% to 3.75% or 1.50% to 2.50%, respectively, for our revolving lines of credit depending on the quarterly adjustments that are based on our consolidated financial performance. The total amount available under our existing credit agreement is \$110.0 million, of which none is outstanding as of March 31, 2007. We recorded interest expense, including amortization of deferred financing costs, under these senior credit facilities in the aggregate amount of \$1.5 million in each of the three months ended March 31, 2007 and 2006.

Borrowings under the senior credit facility are secured by the stock of certain of our U.S. and foreign subsidiaries, substantially all of our intellectual property rights, substantially all of the assets of our businesses in the U.S. and a significant portion of the assets of our businesses outside the U.S. Under the senior credit agreement, as amended, we must comply with various financial and non-financial covenants. The primary financial covenants pertain to, among other things, fixed charge coverage ratio, capital expenditures, various leverage ratios, earnings before interest, taxes, depreciation and amortization (EBITDA) and a minimum cash requirement. Additionally, the senior credit agreement currently prohibits us from paying dividends. As of March 31, 2007, we were in compliance with the covenants.

(14) Defined Benefit Pension Plan

Our subsidiary in England, Unipath Ltd., has a defined benefit pension plan established for certain of its employees. The net periodic benefit costs are as follows (in thousands):

| | Three Months Ended March | |
|--------------------------------|---------------------------------|-------------|
| | 31, | |
| | 2007 | 2006 |
| Service cost | \$ | \$ |
| Interest cost | 150 | 135 |
| Expected return on plan assets | (125) | (112) |
| Realized losses | 86 | 77 |
| Net periodic benefit cost | \$ 111 | \$ 100 |

(15) Financial Information by Segment

Under SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. Our chief operating decision making group is composed of the chief executive officer and members of senior management. Our reportable operating segments are Consumer Diagnostic Products, Vitamins and Nutritional Supplements, Professional Diagnostic Products, and Corporate and Other. Our operating results include license and royalty revenue which are allocated to Consumer Diagnostic Products and Professional Diagnostic Products on the basis of the original license or royalty agreement. Included in the operating loss of Corporate and Other are non-allocable corporate expenditures and expenses related to our research and development activities in the area of cardiology, the latter of which amounted to \$4.7 million, net of the ITI funding (Note 11) of \$4.4 million, and \$5.6 million, net of the ITI funding of \$3.8 million for the three months ended March 31, 2007 and 2006, respectively.

Total assets in the area of cardiology, which are included in Corporate and Other in the tables below, amounted to \$61.8 million at March 31, 2007 and \$51.6 million at December 31, 2006.

We evaluate performance of our operating segments based on revenue and operating income (loss). Segment information for the three months ended March 31, 2006 and 2005 is as follows (in thousands):

| | Consumer Diagnostic Products | Vitamins and Nutritional Supplements | Professional Diagnostic Products | Corporate and Other | Total |
|---------------------------------------|---|---|---|------------------------------------|--------------|
| Three Months Ended March 31, 2007: | | | | | |
| Net revenue to external customers | \$53,569 | \$ 17,784 | \$87,626 | \$ | \$ 158,979 |
| Operating income (loss) | \$ 6,840 | \$ (702) | \$20,206 | \$(11,005) | \$ 15,339 |

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS **Continued**
(unaudited)

| | Consumer Diagnostic Products | Vitamins and Nutritional Supplements | Professional Diagnostic Products | Corporate and Other | Total |
|---------------------------------------|---|---|---|------------------------------------|--------------|
| Three Months Ended March 31, 2006: | | | | | |
| Net revenue to external customers | \$ 43,314 | \$ 19,003 | \$ 65,504 | \$ | \$ 127,821 |
| Operating income (loss) | \$ 8,480 | \$ (1,077) | \$ 9,416 | \$ (11,835) | \$ 4,984 |
| Assets: | | | | | |
| As of March 31, 2007 | \$319,051 | \$52,228 | \$738,886 | \$230,209 | \$1,340,374 |
| As of December 31, 2006 | \$314,815 | \$49,896 | \$625,560 | \$ 95,500 | \$1,085,771 |

(16) Related Party Transactions

On March 22, 2007, we entered into a convertible loan agreement with a related party whereby we loaned the related party £7.5 million (\$14.7 million as of the transaction date). In the event the related party consummates a specific target acquisition on or before September 30, 2007, the loan amount will simultaneously be converted into shares of the related party's stock per the prescribed conversion formula defined in the loan agreement. In the event the related party does not consummate the specific target acquisition by September 30, 2007, the full amount of the loan, plus any accrued interest, will become payable to us on September 30, 2007.

(17) Material Contingencies and Legal Settlements

Due to the nature of our business, we may from time to time be subject to commercial disputes, consumer product claims or various other lawsuits arising in the ordinary course of our business, and we expect this will continue to be the case in the future. These lawsuits generally seek damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, which can be expensive and can result in counterclaims against us. We are currently not a party to any material legal proceedings.

As of March 31, 2007, we had contingent consideration obligations related to our acquisitions of Instant, First Check, Binax, Inc. (Binax) and CLONDIAG chip technologies GmbH (Clondiag). The contingent considerations will be accounted for as increases in the aggregate purchase prices if and when the contingencies occur.

With respect to Instant, the terms of the acquisition agreement provide for \$16.6 million of contingent consideration payable in cash or cash and stock to acquire the remaining 25% ownership interest in Instant. The seller, who is now an employee of Instant, has the option, but is not obligated, to sell his remaining 25% during the four-year period commencing April 1, 2008 and ending March 31, 2012. The option is contingent upon the business meeting certain revenue and gross profit targets or may be triggered should the seller be terminated as an employee, without cause. The option shall terminate if not exercised during the period mentioned above. Furthermore, we have the option, but not an obligation, to acquire the remaining 25% from the seller on or before March 31, 2012 for \$24.6 million in cash or cash and stock. If the seller is no longer an employee of the company at the time of exercise, the full consideration shall be payable in cash. The option shall terminate if not exercised during the period mentioned above.

With respect to First Check, we will pay an earn-out to First Check equal to the incremental revenue growth of the acquired products for 2007 and for the first nine months of 2008, as compared to the immediately preceding comparable periods.

With respect to Binax, the terms of the acquisition agreement provide for \$11.0 million of contingent cash consideration payable to the Binax shareholders upon the successful completion of certain new product developments during the five years following the acquisition.

With respect to Clondiag, the terms of the acquisition agreement provide for \$8.9 million of contingent consideration, consisting of 224,316 shares of our common stock and approximately \$3.0 million of cash or stock in the event that four specified products are developed on Clondiag's platform technology during the three years following the acquisition date.

(18) Recent Accounting Pronouncements

Recently Issued Standards

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application is encouraged. We continue to evaluate the impact that the adoption of SFAS No. 157 will have, if any, on our consolidated financial statements.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
(unaudited)

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB No 115*. This Statement provides companies with an option to measure, at specified election dates, many financial instruments and certain other items at fair value that are not currently measured at fair value. The standard also establishes presentation and disclosure requirements designed to facilitate comparison between entities that choose different measurement attributes for similar types of assets and liabilities. If the fair value option is elected, the effect of the first remeasurement to fair value is reported as a cumulative effect adjustment to the opening balance of retained earnings. The statement is to be applied prospectively upon adoption. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We plan to adopt SFAS No. 159 as of January 1, 2008, and are currently evaluating the impact of SFAS No. 159 on our results of operations or financial position.

Recently Adopted Standards

We adopted FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement 109* on January 1, 2007. FIN 48 clarifies the accounting and reporting for uncertainties in income tax law. This Interpretation prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. See Note 6 for information pertaining to the effects of adoption on our consolidated balance sheet.

In February 2006, the FASB issued SFAS No. 155, *Accounting for Certain Hybrid Financial Instruments*, which amends SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* and SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. SFAS No. 155 simplifies the accounting for certain derivatives embedded in other financial instruments by allowing them to be accounted for as a whole if the holder elects to account for the whole instrument on a fair value basis. SFAS No. 155 also clarifies and amends certain other provisions of SFAS No. 133 and SFAS No. 140. SFAS No. 155 is effective for all financial instruments acquired, issued or subject to a remeasurement event occurring in fiscal years beginning after September 15, 2006. The adoption of SFAS No. 155 did not have any impact on our financial position, results of operations or cash flows.

In June 2006, the FASB ratified the consensus on EITF Issue No. 06-03, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement*. The scope of EITF Issue No. 06-03 includes any tax assessed by a governmental authority that is directly imposed on a revenue-producing transaction between a seller and a customer and may include, but is not limited to, sales, use, value added, Universal Service Fund (USF) contributions and some excise taxes. The Task Force affirmed its conclusion that entities should present these taxes in the income statement on either a gross or a net basis, based on their accounting policy, which should be disclosed pursuant to APB Opinion No. 22, *Disclosure of Accounting Policies*. If such taxes are significant, and are presented on a gross basis, the amounts of those taxes should be disclosed. The consensus on Issue No. 06-03 will be effective for interim and annual reporting periods beginning after December 15, 2006. As required by EITF 06-03, we adopted this new accounting standard for the interim period beginning January 1, 2007. The adoption of EITF 06-03 did not have any impact on our financial position, results of operations or cash flows.

In December 2006, the FASB issued FASB Staff Position (FSP) No. EITF 00-19-2, *Accounting for Registration Payment Arrangements*. This FSP specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5, *Accounting for Contingencies*. The guidance in this FSP amends FASB Statement No. 133, *Accounting for Derivative Financial Instruments and Hedging Activities*, and No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* and FIN 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* to include scope exceptions for registration payment arrangements. This FSP is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified

subsequent to the date of issuance of this FSP. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of this FSP, this guidance shall be effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. As required by EITF 00-19-2, we adopted this new accounting standard on January 1, 2007. The adoption of EITF 00-19-2 did not have any impact on our financial position, results of operations or cash flows.

(19) Guarantor Financial Information

We issued \$150.0 million in senior subordinated notes (the Bonds) to qualified institutional buyers in reliance on Rule 144A under the Securities Act of 1933, as amended (the Securities Act), and outside the United States in compliance with Regulation S of the Securities Act. Our payment obligations under the Bonds are currently guaranteed by all of our domestic subsidiaries (the Guarantor Subsidiaries). The guarantee is full and unconditional. Separate financial statements of the Guarantor Subsidiaries are

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
(unaudited)

not presented because we have determined that they would not be material to investors in the Bonds. The following supplemental financial information sets forth, on a consolidating basis, the statements of operations and cash flows for the three months ended March 31, 2007 and 2006 and the balance sheets as of March 31, 2007 and December 31, 2006 for our company (the Issuer), the Guarantor Subsidiaries and our other subsidiaries (the Non-Guarantor Subsidiaries). The supplemental financial information reflects our investments and the Guarantor Subsidiaries investments in the Guarantor and Non-Guarantor Subsidiaries using the equity method of accounting.

We have extensive transactions and relationships between various members of our consolidated group. These transactions and relationships include intercompany pricing agreements, intellectual property royalty agreements, and general and administrative and research and development cost sharing agreements. Because of these relationships, it is possible that the terms of these transactions are not the same as those that would result from transactions among unrelated parties.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Three Months Ended March 31, 2007

(unaudited)

(in thousands)

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|--|---------------|-----------------------------------|---------------------------------------|---------------------|---------------------|
| Net product sales | \$ 6,857 | \$ 87,266 | \$ 88,886 | \$ (29,260) | \$ 153,749 |
| License and royalty revenue | | 138 | 5,092 | | 5,230 |
| Net revenue | 6,857 | 87,404 | 93,978 | (29,260) | 158,979 |
| Cost of sales | 5,219 | 51,064 | 52,552 | (28,194) | 80,641 |
| Gross profit | 1,638 | 36,340 | 41,426 | (1,066) | 78,338 |
| Operating expenses: | | | | | |
| Research and development | 321 | 1,938 | 9,750 | | 12,009 |
| Sales and marketing | 1,254 | 14,806 | 12,271 | | 28,331 |
| General and administrative | 5,899 | 6,105 | 10,655 | | 22,659 |
| Total operating expenses | 7,474 | 22,849 | 32,676 | | 62,999 |
| Operating (loss) income | (5,836) | 13,491 | 8,750 | (1,066) | 15,339 |
| Equity in earnings (losses) of subsidiaries, net of tax | 9,738 | | | (9,738) | |
| Interest expense, including amortization of original issue discounts and write-off of deferred financing costs | (3,478) | (930) | (7,982) | 7,206 | (5,184) |
| Other income (expense), net | 7,288 | 1,415 | 595 | (7,269) | 2,029 |
| Income (loss) before provision for income taxes | 7,712 | 13,976 | 1,363 | (10,867) | 12,184 |
| Provision for income taxes | 1,407 | 3,441 | 1,031 | | 5,879 |
| Net income (loss) | \$ 6,305 | \$ 10,535 | \$ 332 | \$ (10,867) | \$ 6,305 |

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Three Months Ended March 31, 2006

(unaudited)

(in thousands)

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|--|---------------|-----------------------------------|---------------------------------------|---------------------|---------------------|
| Net product sales | \$ 5,887 | \$ 72,877 | \$ 61,252 | \$ (17,263) | \$ 122,753 |
| License and royalty revenue | | 71 | 4,997 | | 5,068 |
| Net revenue | 5,887 | 72,948 | 66,249 | (17,263) | 127,821 |
| Cost of sales | 6,697 | 51,012 | 34,929 | (17,071) | 75,567 |
| Gross profit | (810) | 21,936 | 31,320 | (192) | 52,254 |
| Operating expenses: | | | | | |
| Research and development | 983 | 1,928 | 7,699 | | 10,610 |
| Sales and marketing | 1,302 | 10,084 | 9,436 | | 20,822 |
| General and administrative | 5,152 | 3,876 | 6,810 | | 15,838 |
| Total operating expenses | 7,437 | 15,888 | 23,945 | | 47,270 |
| Operating (loss) income | (8,247) | 6,048 | 7,375 | (192) | 4,984 |
| Equity in earnings (losses) of subsidiaries, net of tax | 7,271 | | | (7,271) | |
| Interest expense, including amortization of original issue discounts and write-off of deferred financing costs | (4,079) | (796) | (2,523) | 1,677 | (5,721) |
| Other income (expense), net | 2,703 | (99) | (1,355) | (1,677) | (428) |
| (Loss) income before provision for income taxes | (2,352) | 5,153 | 3,497 | (7,463) | (1,165) |
| Provision for income taxes | 278 | 554 | 633 | | 1,465 |
| Net (loss) income | \$ (2,630) | \$ 4,599 | \$ 2,864 | \$ (7,463) | \$ (2,630) |

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING BALANCE SHEET

March 31, 2007

(unaudited)

(in thousands)

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|--|---------------------|-----------------------------------|---------------------------------------|-----------------------|---------------------|
| ASSETS | | | | | |
| Current Assets: | | | | | |
| Cash and cash equivalents | \$ 104,301 | \$ 33,728 | \$ 42,912 | \$ | \$ 180,941 |
| Accounts receivable, net of allowances | 2,908 | 50,101 | 46,867 | | 99,876 |
| Inventories, net | 6,567 | 44,245 | 41,174 | (4,655) | 87,331 |
| Deferred tax assets | | | 5,416 | | 5,416 |
| Related party note receivable | | | 14,733 | | 14,733 |
| Prepaid expenses and other current assets | 2,915 | 2,668 | 16,340 | | 21,923 |
| Intercompany receivables | 65,257 | 76,379 | 15,223 | (156,859) | |
| Total current assets | 181,948 | 207,121 | 182,665 | (161,514) | 410,220 |
| Property, plant and equipment, net | 1,976 | 23,556 | 55,798 | | 81,330 |
| Goodwill | 107,663 | 117,864 | 263,908 | | 489,435 |
| Other intangible assets with indefinite lives | | 21,120 | 47,282 | | 68,402 |
| Core technology and patents, net | 18,053 | 12,861 | 56,651 | | 87,565 |
| Other intangible assets, net | 26,262 | 41,908 | 37,199 | | 105,369 |
| Deferred financing costs, net and other non-current assets | 6,979 | 1,871 | 4,251 | | 13,101 |
| Other investments and available-for-sale securities | 455,110 | (663) | 9,511 | (380,044) | 83,914 |
| Deferred tax assets | 122 | 4,327 | (3,411) | | 1,038 |
| Intercompany notes receivable | 458,322 | 56,267 | | (514,589) | |
| Total assets | \$ 1,256,435 | \$ 486,232 | \$ 653,854 | \$ (1,056,147) | \$ 1,340,374 |
| LIABILITIES AND STOCKHOLDERS EQUITY | | | | | |
| Current liabilities: | | | | | |
| Current portion of long-term debt | \$ | \$ | \$ 8,876 | \$ | \$ 8,876 |
| Current portion of capital lease obligations | | 562 | 35 | | 597 |

Edgar Filing: INVERNESS MEDICAL INNOVATIONS INC - Form 10-Q

| | | | | | |
|---|---------------------|-------------------|-------------------|-----------------------|---------------------|
| Accounts payable | 5,340 | 16,675 | 20,883 | | 42,898 |
| Accrued expenses and other current liabilities | 20,498 | 16,838 | 33,365 | | 70,701 |
| Intercompany payables | 45,284 | 40,002 | 71,564 | (156,850) | |
| Total current liabilities | 71,122 | 74,077 | 134,723 | (156,850) | 123,072 |
| Long-term liabilities: | | | | | |
| Long-term debt, net of current portion | 150,000 | | 132 | | 150,132 |
| Capital lease obligations, net of current portion | | 214 | 45 | | 259 |
| Deferred tax liabilities | 8,515 | 15,042 | 5,031 | | 28,588 |
| Other long-term liabilities | 119 | 291 | 11,178 | 56 | 11,644 |
| Intercompany notes payable | | 159,277 | 355,315 | (514,592) | |
| Total long-term liabilities | 158,634 | 174,824 | 371,701 | (514,536) | 190,623 |
| Stockholders equity | 1,026,679 | 237,331 | 147,430 | (384,761) | 1,026,679 |
| Total liabilities and stockholders equity | \$ 1,256,435 | \$ 486,232 | \$ 653,854 | \$ (1,056,147) | \$ 1,340,374 |

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING BALANCE SHEET

December 31, 2006

(unaudited)

(in thousands)

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|--|-------------------|-----------------------------------|---------------------------------------|---------------------|---------------------|
| ASSETS | | | | | |
| Current Assets: | | | | | |
| Cash and cash equivalents | \$ 16,350 | \$ 19,755 | \$ 34,999 | \$ | \$ 71,104 |
| Accounts receivable, net of allowances | 2,538 | 53,544 | 44,306 | | 100,388 |
| Inventories, net | 5,984 | 38,804 | 37,116 | (3,582) | 78,322 |
| Deferred tax assets | | | 5,332 | | 5,332 |
| Prepaid expenses and other current assets | 2,238 | 2,444 | 15,716 | | 20,398 |
| Intercompany receivables | 57,748 | 67,589 | 8,542 | (133,879) | |
| Total current assets | 84,858 | 182,136 | 146,011 | (137,461) | 275,544 |
| Property, plant and equipment, net | 2,098 | 24,710 | 55,504 | | 82,312 |
| Goodwill | 71,136 | 109,116 | 259,117 | | 439,369 |
| Other intangible assets with indefinite lives | | 21,120 | 46,987 | | 68,107 |
| Core technology and patents, net | 18,496 | 13,304 | 55,932 | | 87,732 |
| Other intangible assets, net | 14,321 | 31,098 | 38,375 | | 83,794 |
| Deferred financing costs, net and other non-current assets | 6,314 | 2,277 | 4,627 | | 13,218 |
| Other investments and available-for-sale securities | 387,818 | (778) | 10,835 | (362,258) | 35,617 |
| Deferred tax assets | | | 78 | | 78 |
| Intercompany notes receivable | 355,074 | 56,267 | | (411,341) | |
| Total assets | \$ 940,115 | \$ 439,250 | \$ 617,466 | \$ (911,060) | \$ 1,085,771 |
| LIABILITIES AND STOCKHOLDERS EQUITY | | | | | |
| Current liabilities: | | | | | |
| Current portion of long-term debt | \$ | \$ 450 | \$ 7,054 | \$ | \$ 7,504 |
| Current portion of capital lease obligations | | 551 | 33 | | 584 |
| Accounts payable | 5,302 | 19,998 | 21,042 | | 46,342 |
| | 24,920 | 19,721 | 42,642 | 518 | 87,801 |

Edgar Filing: INVERNESS MEDICAL INNOVATIONS INC - Form 10-Q

| | | | | | |
|---|-------------------|-------------------|-------------------|---------------------|---------------------|
| Accrued expenses and other current liabilities | | | | | |
| Intercompany payables | 40,803 | 35,967 | 60,179 | (136,949) | |
| Total current liabilities | 71,025 | 76,687 | 130,950 | (136,431) | 142,231 |
| Long-term liabilities: | | | | | |
| Long-term debt, net of current portion | 150,000 | 44,325 | 148 | | 194,473 |
| Capital lease obligations, net of current portion | | 360 | 55 | | 415 |
| Deferred tax liabilities | 4,903 | 8,149 | 10,932 | | 23,984 |
| Other long-term liabilities | 49 | 305 | 10,176 | | 10,530 |
| Intercompany notes payable | | 85,983 | 322,275 | (408,258) | |
| Total long-term liabilities | 154,952 | 139,122 | 343,586 | (408,258) | 229,402 |
| Stockholders equity | 714,138 | 223,441 | 142,930 | (366,371) | 714,138 |
| Total liabilities and stockholders equity | \$ 940,115 | \$ 439,250 | \$ 617,466 | \$ (911,060) | \$ 1,085,771 |

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS

For the Three Months Ended March 31, 2007

(unaudited)

(in thousands)

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|-----------------|---------------------------|-------------------------------|--------------|--------------|
| Cash Flows from Operating Activities: | | | | | |
| Net income (loss) | \$ 6,305 | \$ 10,535 | \$ 332 | \$ (10,867) | \$ 6,305 |
| Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities: | | | | | |
| Equity in earnings of subsidiaries, net of tax | (9,738) | | | 9,738 | |
| Interest expense related to amortization and write-off of non-cash original issue discount and deferred financing costs | 187 | 492 | 460 | | 1,139 |
| Non-cash stock-based compensation expense | 1,593 | | | | 1,593 |
| Loss on sale of fixed assets | 50 | | | | 50 |
| Interest in minority investments | (276) | | (160) | | (436) |
| Depreciation and amortization | 1,234 | 3,891 | 6,004 | | 11,129 |
| Deferred and other non-cash income taxes | 899 | 3,375 | (478) | | 3,796 |
| Other non-cash items | 96 | | | | 96 |
| Changes in assets and liabilities, net of acquisitions: | | | | | |
| Accounts receivable, net | (370) | 8,650 | 1,204 | | 9,484 |
| Inventories, net | (583) | (355) | (3,330) | 1,073 | (3,195) |
| Prepaid expenses and other current assets | (677) | (47) | (694) | | (1,418) |
| Intercompany (receivable) payable | (61,119) | 23,834 | 38,280 | (995) | |
| Accounts payable | 36 | (7,010) | (1,093) | | (8,067) |
| Accrued expenses and other current liabilities | (5,052) | (3,990) | (4,832) | | (13,874) |
| Other non-current liabilities | 71 | (14) | 825 | 56 | 938 |
| Net cash (used in) provided by operating activities | (67,344) | 39,361 | 36,518 | (995) | 7,540 |

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS (Continued)

For the Three Months Ended March 31, 2007

(unaudited)

(in thousands)

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|-----------------|-----------------------------------|---------------------------------------|---------------------|---------------------|
| Cash Flows from Investing Activities: | | | | | |
| Purchases of property, plant and equipment | \$ (198) | \$ (683) | \$ (2,194) | \$ | \$ (3,075) |
| Proceeds from sale of equipment | | 30 | 8 | | 38 |
| Note receivable with related party | | | (14,733) | | (14,733) |
| Cash paid for acquisitions and transactional costs, net of cash acquired | (31,875) | (24,439) | (11,846) | | (68,160) |
| Cash paid for minority interest investments and available-for-sale securities | (26,276) | (50) | 724 | | (25,602) |
| Increase in other assets | (909) | (62) | (906) | | (1,877) |
| Net cash used in investing activities | (59,258) | (25,204) | (28,947) | | (113,409) |
| Cash Flows from Financing Activities: | | | | | |
| Cash paid for financing costs | (39) | (49) | (49) | | (137) |
| Proceeds from issuance of common stock, net of issuance costs | 264,132 | | | | 264,132 |
| Net proceeds under revolving line of credit | | | 68 | | 68 |
| Tax benefit on exercised stock options | 160 | | | | 160 |
| Repayments of notes payable | (4,925) | (44,775) | | | (49,700) |
| Principal payments of capital lease obligations | | (135) | (8) | | (143) |
| Intercompany notes (receivable) payable | (44,775) | 44,775 | | | |
| Net cash provided by (used in) financing activities | 214,553 | (184) | 11 | | 214,380 |
| Foreign exchange effect on cash and cash equivalents | | | 331 | 995 | 1,326 |

| | | | | |
|---|------------|-----------|-----------|------------|
| Net increase in cash and cash equivalents | 87,951 | 13,973 | 7,913 | 109,837 |
| Cash and cash equivalents, beginning of period | 16,350 | 19,755 | 34,999 | 71,104 |
| Cash and cash equivalents, end of period | \$ 104,301 | \$ 33,728 | \$ 42,912 | \$ 180,941 |

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS

For the Three Months Ended March 31, 2006

(unaudited)

(in thousands)

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|----------------|-----------------------------------|---------------------------------------|---------------------|---------------------|
| Cash Flows from Operating Activities: | | | | | |
| Net (loss) income | \$ (2,630) | \$ 4,599 | \$ 2,864 | \$ (7,463) | \$ (2,630) |
| Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities: | | | | | |
| Equity in earnings of subsidiaries, net of tax | (7,271) | | | 7,271 | |
| Interest expense related to amortization and write-off of non-cash original issue discount and deferred financing costs | 296 | 216 | 165 | | 677 |
| Non-cash loss related to currency hedge | (217) | | | | (217) |
| Non-cash stock-based compensation expense | 1,318 | | | | 1,318 |
| Depreciation and amortization | 1,603 | 2,337 | 3,706 | | 7,646 |
| Deferred income taxes | 196 | 546 | 1 | | 743 |
| Other non-cash items | 159 | 18 | (36) | | 141 |
| Changes in assets and liabilities, net of acquisitions: | | | | | |
| Accounts receivable, net | (288) | (2,291) | (3,729) | | (6,308) |
| Inventories, net | 80 | 3,873 | 268 | 192 | 4,413 |
| Prepaid expenses and other current assets | (1,589) | 84 | 725 | | (780) |
| Intercompany (receivable) payable | (1,474) | 4,887 | (2,097) | (1,316) | |
| Accounts payable | 3,645 | (9,205) | (1,807) | | (7,367) |
| Accrued expenses and other current liabilities | (3,256) | (1,984) | 771 | | (4,469) |
| Other non-current liabilities | | 7 | 84 | | 91 |
| Net cash (used in) provided by operating activities | (9,428) | 3,087 | 915 | (1,316) | (6,742) |

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued
INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS (Continued)

For the Three Months Ended March 31, 2006

(unaudited)
(in thousands)

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|--|-----------------|-----------------------------------|---------------------------------------|---------------------|---------------------|
| Cash Flows from Investing Activities: | | | | | |
| Purchases of property, plant and equipment | \$ (135) | \$ (1,093) | \$ (3,121) | \$ | \$ (4,349) |
| Proceeds from sale of equipment | | 6 | 27 | | 33 |
| Cash paid for acquisitions and transactional costs, net of cash acquired | (58,584) | (26) | (11,559) | | (70,169) |
| Decrease (increase) in other assets | 1,122 | (16) | (66) | | 1,040 |
| Net cash used in investing activities | (57,597) | (1,129) | (14,719) | | (73,445) |
| Cash Flows from Financing Activities: | | | | | |
| Cash paid for financing costs | 8 | (167) | (157) | | (316) |
| Proceeds from issuance of common stock, net of issuance costs | 82,128 | | | | 82,128 |
| Net payments under revolving line of credit | | (2,000) | (1,654) | | (3,654) |
| Repayments of notes payable | | | (42) | | (42) |
| Principal payments of capital lease obligations | | (128) | (9) | | (137) |
| Intercompany notes (receivable) payable | (16,000) | 2,000 | 14,000 | | |
| Net cash provided by (used in) financing activities | 66,136 | (295) | 12,138 | | 77,979 |
| Foreign exchange effect on cash and cash equivalents | | | 147 | 1,316 | 1,463 |
| Net (decrease) increase in cash and cash equivalents | (889) | 1,663 | (1,519) | | (745) |
| Cash and cash equivalents, beginning of period | 1,195 | 8,080 | 24,995 | | 34,270 |
| | \$ 306 | \$ 9,743 | \$ 23,476 | \$ | \$ 33,525 |

**Cash and cash equivalents, end of
period**

24

Table of Contents**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****Financial Overview**

As a leading global manufacturer and supplier of rapid diagnostic products for consumer and professional markets, we are continually exploring new opportunities for our proprietary electrochemical and other technologies in a variety of professional diagnostic and consumer-oriented applications, including immuno-diagnostics with a focus on women's health, cardiology and infectious disease. As part of this strategy, we are focused on opportunities, including acquisitions and strategic partnerships, aimed at expanding both our product offerings and the worldwide distribution network supporting our professional diagnostic segment. We are also focused on improving our margins through consolidation of certain of our manufacturing operations at lower cost facilities. Our acquisition of the Innovacon business represents a key component of this strategy. During the first quarter of 2007, we saw improved margins on some of our existing products as we move production of certain products from higher cost facilities to our ABON facility in Hangzhou, China.

Our agreement with The Procter and Gamble Company (P&G) to form a 50/50 joint venture for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products outside of the fields of cardiology and diabetes remains on track and is expected to close in the second or third quarter of 2007. By leveraging P&G's sales and distribution capabilities, we expect this partnership to simultaneously expand the reach of our over-the-counter diagnostic products, while enabling enhanced focus on our rapidly growing professional diagnostics segment and, in particular, on our cardiology development programs.

We are continuing our efforts to acquire Biosite Incorporated, or Biosite, and we have recently made a binding offer to acquire by way of a cash tender offer all of Biosite's outstanding common stock for \$92.50 per share. We believe that a combination with us would provide significant benefits to the public, particularly in the area of cardiology diagnostics, and to our shareholders. The risks associated with our efforts to acquire Biosite, and Biosite's agreement to merge with Beckman Coulter, Inc., or Beckman Coulter, are discussed in Part II, Item 1A, Risk Factors, on page 37 of this report.

We continue to emphasize new product development. This requires substantial investment and involves significant inherent risk. We intend to continue to devote substantial resources to research and development activities. We also continue to aggressively defend our substantial intellectual property portfolio, which underlies our emphasis on new product development, against potential infringers.

For the three months ended March 31, 2007, we recorded net revenue of \$159.0 million, compared to \$127.8 million for the three months ended March 31, 2006, representing a 24% increase with acquisitions accounting for \$18.9 million of the increase. The organic growth in revenue excluding acquisitions was approximately 10% and currency adjusted organic growth was 7% on an overall basis and 9% in our core diagnostic business. Adjusted for the favorable impact of currency translation, net revenue of \$154.9 million for the first quarter of 2007 was approximately 21% higher than for the first quarter of 2006. Our nutritional business experienced a 6% decrease in net product revenue from the first quarter of 2006.

For the three months ended March 31, 2007, we generated a net income of \$6.3 million, compared to a net loss of \$2.6 million for the three months ended March 31, 2006. The improvement in net income for the first quarter of 2007, compared to the first quarter of 2006, resulted primarily from an increase in revenues from our diagnostics business largely due to our recent acquisitions of the Innovacon business, Instant Technologies, Inc. and First Check Diagnostics LLC.

Results of Operations

Net Product Sales, Total and by Business Segment. Total net product sales increased by \$31.0 million, or 25%, to \$153.7 million for the three months ended March 31, 2007 from \$122.8 million for the three months ended March 31, 2006. Excluding the favorable impact of currency translation, net product sales for the three months ended March 31, 2007 increased by \$27.0 million, compared to the three months ended March 31, 2006. Net product sales by business segment for the three months ended March 31, 2007 and 2006 are as follows (in thousands):

%

| | Three Months Ended March | | |
|--------------------------------------|---------------------------------|-------------|---------------|
| | 31, | | |
| | 2007 | 2006 | Change |
| Consumer diagnostic products | \$ 52,138 | \$ 41,198 | 27% |
| Vitamins and nutritional supplements | 17,784 | 19,003 | (6)% |
| Professional diagnostic products | 83,827 | 62,552 | 34% |
| Total net product sales | \$ 153,749 | \$ 122,753 | 25% |

Consumer Diagnostic Products

Net product sales of our consumer diagnostic products increased by \$10.9 million, or 27%, comparing the three months ended March 31, 2007 to the three months ended March 31, 2006. Organic growth in our premium

Table of Contents

pregnancy test products was a primary contributor to this increase, along with our acquisitions of the Innovacon business in March 2006 and First Check in January 2007, which contributed \$1.8 million and \$2.2 million, respectively, in net product sales.

Vitamins and Nutritional Supplements

Our vitamins and nutritional supplements net product sales decreased by \$1.2 million, or 6%, comparing the three months ended March 31, 2007 to the three months ended March 31, 2006.

Professional Diagnostic Products

Net product sales of our professional diagnostic products increased by \$21.3 million, or 34%, comparing the three months ended March 31, 2007 to the three months ended March 31, 2006. Excluding the impact from currency translation, net product sales of our professional diagnostic products increased by \$19.7 million, or 31%, comparing the three months ended March 31, 2007 to the three months ended March 31, 2006. Of the currency adjusted increase, net product sales increased as a result of our acquisitions of: (i) the Innovacon business in March 2006, which contributed \$10.3 million of such increase, (ii) Instant in March 2007, which contributed \$1.6 million of such increase and (iii) various less significant acquisitions, which contributed an aggregate of \$3.1 million of such increase. Organic growth also contributed to the increase as we continued to gain market share particularly with our highly differentiated, higher margin brands such as BinaxNOW[®] and TestPack[®].

License and Royalty Revenue. License and royalty revenue represents license and royalty fees from intellectual property license agreements with third parties. License and royalty revenue increased by approximately \$0.2 million, or 3%, to \$5.2 million for the three months ended March 31, 2007 from \$5.1 million for the three months ended March 31, 2006. The increase primarily relates to the Vedalab royalty earned during the three months ended March 31, 2007.

Gross Profit and Margin. Gross profit increased by \$26.1 million, or 50%, to \$78.3 million for the three months ended March 31, 2007 from \$52.3 million for the three months ended March 31, 2006. Gross profit during the three months ended March 31, 2007 benefited primarily from higher than average margins earned on revenue from our recently acquired businesses, as discussed above. Gross profit for the three months ended March 31, 2006 included a \$0.7 million restructuring charge related to the closure of our Galway, Ireland manufacturing facility.

Cost of sales included amortization expense of \$3.0 million and \$2.0 million for the three months ended March 31, 2007 and March 31, 2006, respectively.

Overall gross margin for the three months ended March 31, 2007 was 49%, compared to 41% for the three months ended March 31, 2006.

Gross Profit from Net Product Sales by Business Segment. Gross profit from net product sales represents total gross profit less gross profit associated with license and royalty revenue. Gross profit from total net product sales increased by \$27.6 million, or 57%, to \$76.2 million for the three months ended March 31, 2007 from \$48.6 million for the three months ended March 31, 2006. Gross profit from net product sales by business segment for the three months ended March 31, 2007 and 2006 are as follows (in thousands):

| | Three Months Ended March | | % Change |
|---|---------------------------------|-------------|---------------------|
| | 2007 | 2006 | |
| Consumer diagnostic products | \$ 28,450 | \$ 20,296 | 40% |
| Vitamins and nutritional supplements | 1,254 | 834 | 50% |
| Professional diagnostic products | 46,461 | 27,434 | 69% |
| Total gross profit from net product sales | \$ 76,165 | \$ 48,564 | 57% |

Consumer Diagnostic Products

Gross profit from our consumer diagnostic product sales increased by \$8.2 million, or 40%, to \$28.5 million for the first quarter of 2007, compared to \$20.3 million for the first quarter of 2006. The increase is primarily a result of gross profit earned on revenue from acquired businesses and the revenue increase due to organic growth, as discussed

above. Included in cost of sales for the three months ended March 31, 2006 is a \$0.7 million restructuring charge related to the closure of our Galway, Ireland manufacturing facility.

As a percentage of our consumer diagnostic net product sales, gross margin for the three months ended March 31, 2007 was 55%, compared with a gross margin percentage of 51% for the three months ended March 31, 2006.

Table of Contents*Vitamins and Nutritional Supplements*

Gross profit in our vitamins and nutritional supplements business increased by \$0.5 million, or 50%, to \$1.3 million from \$0.8 million, comparing the three months ended March 31, 2007 to the three months ended March 31, 2006. The increase is primarily the result of improved factory utilization and our cost reduction initiatives in our private label manufacturing business.

As a percentage of net product sales, gross margin for our vitamins and nutritional supplements business was approximately 7% and 4%, for the three months ended March 31, 2007 and 2006, respectively.

Professional Diagnostic Products

Gross profit from our professional diagnostic product sales increased by \$19.0 million, or 69%, to \$46.5 million during the three months ended March 31, 2007, compared to \$27.4 million for the three months ended March 31, 2006. The increase in gross profit is largely attributable to the increase in product sales resulting primarily from our acquisition of the Innovacon business, where higher margin products are manufactured and our recent acquisition of Instant.

As a percentage of our professional diagnostic net product sales, gross margin for the three months ended March 31, 2007 and 2006 was 55% and 44%, respectively.

Research and Development Expense. Research and development expense increased by \$1.4 million, or 13%, to \$12.0 million for the three months ended March 31, 2007 from \$10.6 million for the three months ended March 31, 2006. The increase was primarily the result of increased spending related to our cardiology and consumer research programs. Research and development expense of \$12.0 million for the first quarter of 2007 was partially offset by \$4.4 million of funding from ITI earned during the quarter, which represented an increase in funding of \$0.5 million over the comparable quarter in 2006, and \$0.5 million of unfavorable impact resulting from foreign currency translation.

Amortization expense of \$0.8 million and \$0.7 million was included in research and development expense for the three months ended March 31, 2007 and 2006, respectively.

Research and development expense as a percentage of net product sales decreased to 8% for the three months ended March 31, 2007, compared to 9% for the three months ended March 31, 2006.

Sales and Marketing Expense. Sales and marketing expense increased by \$7.5 million, or 36%, to \$28.3 million for the three months ended March 31, 2007 from \$20.8 million for the three months ended March 31, 2006. The increase in sales and marketing expense was primarily the result of approximately \$3.0 million of additional spending related to our acquisitions, primarily the Innovacon business, First Check, Instant and various less significant acquisitions, and higher advertising expenditures associated with the introduction of our next generation branded digital pregnancy test, partially offset by a \$0.6 million of unfavorable impact resulting from foreign currency translation.

Amortization expense of \$2.5 million and \$1.2 million was included in sales and marketing expense for the three months ended March 31, 2007 and 2006, respectively.

Sales and marketing expense as a percentage of net product sales increased to 18% for the three months ended March 31, 2007, compared to 17% for the three months ended March 31, 2006.

General and Administrative Expense. General and administrative expense increased by approximately \$6.8 million, or 43%, to \$22.7 million for the three months ended March 31, 2007 from \$15.8 million for the three months ended March 31, 2006. The increase in general and administrative expense included approximately \$2.2 million of additional spending related to our acquisitions of the Innovacon business, First Check, Instant and the various less significant acquisitions and a \$0.5 million restructuring charge related to the closure of our San Diego, California manufacturing facility, offset by a decrease in legal spending of \$1.2 million and a \$0.7 million of unfavorable impact resulting from foreign currency translation.

Amortization expense of \$0.1 million and \$0.1 million was included in general and administrative expense for the three months ended March 31, 2007 and 2006, respectively.

General and administrative expense as a percentage of net revenue increased to 14% for the three months ended March 31, 2007, compared to 12% for the three months ended March 31, 2006.

Table of Contents

Interest Expense. Interest expense includes interest charges, the write-off and amortization of deferred financing costs and the amortization of non-cash discounts associated with our debt issuances. Interest expense decreased by \$0.5 million, or 9%, to \$5.2 million for the three months ended March 31, 2007 from \$5.7 million for the three months ended March 31, 2006. Such decrease was primarily due to a lower average outstanding debt balance which was \$181.4 million during the three months ended March 31, 2007, compared to \$260.7 million during the three months ended March 31, 2006, as a result of repayments against outstanding borrowings in January 2007. Interest expense for the three months ended March 31, 2007 included the write off of \$0.2 million of non-cash deferred financing costs related to the repayment of our outstanding debt.

Other Income (Expense), Net. Other income (expense), net includes interest income, realized and unrealized foreign exchange gains and losses, and other income and expense. The components and the respective amounts of other income (expense), net are summarized as follows (in thousands):

| | Three Months Ended March | | \$ Change |
|-----------------------------------|--------------------------|-------------|--------------|
| | 2007 | 31, 2006 | |
| Interest income | \$ 1,697 | \$ 333 | \$ 1,364 |
| Foreign exchange losses, net | (474) | (1,610) | 1,136 |
| Other | 806 | 849 | (43) |
| Total other income (expense), net | \$ 2,029 | \$ (428) | \$ 2,457 |

Interest income of \$1.7 million for the three months ended March 31, 2007 increased \$1.4 million compared to the three months ended March 31, 2006. This increase is primarily the result of interest earned on higher cash balances. Other income of \$0.8 million for the three months ended March 31, 2007, includes a \$0.8 million gain which resulted from a favorable adjustment to the rental terms of one of our leased facilities.

Included in the foreign exchange losses, net for the three months ended March 31, 2006 was a \$1.2 million unrealized foreign exchange loss associated with the closure of our Galway, Ireland manufacturing facility. Other income of \$0.8 million included \$0.2 million of income related to a foreign currency exchange contract, a \$0.8 million gain on a legal settlement related to the resolution of a contingency related to our 2003 acquisition of Applied Biotech, Inc. (ABI), and \$0.2 million of additional expense related to a legal settlement of a class action suit against several raw material suppliers in our vitamins and nutritional supplements business.

Provision for Income Taxes. Provision for income taxes was \$5.9 million for the three months ended March 31, 2007, an increase of \$4.4 million from \$1.5 million for the three months ended March 31, 2006. The effective tax rate was 48% for the three months ended March 31, 2007, compared to (126)% for the three months ended March 31, 2006. The income tax provision for the three months ended March 31, 2007 is primarily related to the utilization of acquired U.S. and foreign net operating loss carryforwards, state income tax provision and foreign income tax provision for various foreign subsidiaries. The utilization of acquired net operating loss carryforwards does not reduce the income tax provision but rather reduces the goodwill related to the acquired business. The income tax provision increase is primarily due to the use of acquired net operating loss carryforwards. The income tax provision for the three month period ending March 31, 2006 is primarily related to the recognition of U.S. deferred tax liabilities for temporary differences between the book and tax basis of goodwill and certain intangible assets with indefinite lives, state income tax provision and foreign income tax provisions for various foreign subsidiaries.

Net Income (Loss). We earned net income of \$6.3 million, or \$0.14 per basic and diluted common share, for the three months ended March 31, 2007, compared to a net loss of \$2.6 million, or \$0.09 per basic and diluted common share, for the three months ended March 31, 2006. The increase in net income for the three months ended March 31, 2007, compared to the three months ended March 31, 2006, primarily resulted from the various factors as discussed above. See Note 5 of the accompanying consolidated financial statements for the calculation of net income (loss) per common share.

Liquidity and Capital Resources

Based upon our current working capital position, current operating plans and expected business conditions, we believe that our existing capital resources, credit facilities and expected funding resulting from our co-development funding agreement with ITI will be adequate to fund our operations, including our outstanding debt and other commitments, as discussed below, for the next 12 months. In the long run, we expect to fund our working capital needs and other commitments primarily through our operating cash flow, which we expect to improve as we improve our operating margins and grow our business through new product introductions and by continuing to leverage our strong intellectual property position. We also expect to rely on our credit facilities to fund a portion of our capital needs and other commitments.

Our funding plans for our working capital needs and other commitments may be adversely impacted by unexpected costs associated with prosecuting and defending our existing lawsuits and/or unforeseen lawsuits against us, integrating the operations of

Table of Contents

newly acquired companies and executing our cost savings strategies. We also cannot be certain that our underlying assumed levels of revenues and expenses will be realized. In addition, we intend to continue to make significant investments in our research and development efforts related to the substantial intellectual property portfolio we own. We may also choose to further expand our research and development efforts and may pursue the acquisition of new products and technologies through licensing arrangements, business acquisitions, or otherwise. We may also choose to make significant investment to pursue legal remedies against potential infringers of our intellectual property. If we decide to engage in such activities, or if our operating results fail to meet our expectations, we could be required to seek additional funding through public or private financings or other arrangements. In such event, adequate funds may not be available when needed, or, may be available only on terms which could have a negative impact on our business and results of operations. In addition, if we raise additional funds by issuing equity or convertible securities, dilution to then existing stockholders may result.

Summary of Changes in Cash Position

As of March 31, 2007, we had cash and cash equivalents of \$180.9 million, a \$109.8 million increase from December 31, 2006. Our primary sources of cash during the three months ended March 31, 2007, included \$264.1 million in proceeds from the issuance of our common stock in connection with our January 2007 offering, as well as common stock issues under employee stock option and stock purchase plans, and \$7.5 million of cash generated by our operating activities. Investing activities during the three months ended March 31, 2007 used a total of \$113.4 million of cash. Our non-equity financing activities, primarily included repayments under our primary senior credit facility which used \$49.7 million of cash during the three months ended March 31, 2007. Fluctuations in foreign currencies favorably impacted our cash balance by \$1.3 million during the three months ended March 31, 2007.

Cash Flows from Operating Activities

Net cash provided by operating activities during the three months ended March 31, 2007 was \$7.5 million, which resulted from our net income of \$6.3 million and \$17.4 million of non-cash items, of which \$11.1 million related to depreciation and amortization, offset by approximately \$16.2 million of cash associated with an increase in working capital.

Cash Flows from Investing Activities

Our investing activities during the three months ended March 31, 2007 utilized \$113.4 million of cash, including \$68.2 million used for acquisitions and transaction-related costs, net of cash acquired, \$25.6 million related to purchases of available-for-sale securities, netted with our minority investment activities, \$14.7 million used to extend a loan to a related party, \$3.0 million of capital expenditures, net of proceeds from sale of equipment and a \$1.9 million increase in other assets.

Significant acquisitions during the first quarter of 2007 included First Check and Instant, which accounted for approximately \$55.5 million of the \$68.2 million in cash used for acquisitions.

Cash Flows from Financing Activities

On January 31, 2007, we sold an aggregate 6,000,000 shares of our common stock at \$39.65 per share through an underwritten public offering, and on February 5, 2007, our underwriters exercised in full an option to purchase an additional 900,000 shares to cover over-allotments. Proceeds from the offering were approximately \$261.3 million, net of issuance costs of \$12.3 million, which include deductions for underwriting discounts and commissions and take into effect the reimbursement by the underwriters of a portion of our offering expenses. Of this amount, we used \$44.9 million to repay all principal and accrued interest owing on the term loan under our senior credit facility, with the remainder of the net proceeds retained for working capital and other general corporate purposes.

As of March 31, 2007, we had an aggregate of \$0.9 million in outstanding capital lease obligations which are payable through 2011.

Income Taxes

As of December 31, 2006, we had approximately \$188.7 million of domestic net operating loss (NOL) carryforwards and \$31.5 million of foreign NOL carryforwards, respectively, which either expire on various dates through 2026 or can be carried forward indefinitely. These losses are available to reduce federal and foreign taxable income, if any, in future years. These losses are also subject to review and possible adjustments by the applicable

taxing authorities. In addition, the domestic operating loss carryforward amount at December 31, 2006 included approximately \$70.5 million of pre-acquisition losses at IMN, Ischemia, Ostex and Advantage Diagnostics Corporation (ADC) and the foreign operating loss carryforward amount included approximately \$12.7 million of pre-acquisition losses at Clondiag. The future benefit of these losses will be applied first to reduce to zero any goodwill and other non-current intangible assets related to the acquisitions, prior to reducing our income tax expense. Also included in our domestic

Table of Contents

NOL carryforwards at December 31, 2006 was approximately \$2.6 million resulting from the exercise of employee stock options, the tax benefit of which, when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax.

Furthermore, all domestic losses are subject to the Internal Revenue Service Code Section 382 limitation and may be limited in the event of certain cumulative changes in ownership interests of significant shareholders over a three-year period in excess of 50%. Section 382 imposes an annual limitation on the use of these losses to an amount equal to the value of the company at the time of the ownership change multiplied by the long term tax exempt rate. We have recorded a valuation allowance against a portion of the deferred tax assets related to our net operating losses and certain of our other deferred tax assets to reflect uncertainties that might affect the realization of such deferred tax assets, as these assets can only be realized via profitable operations.

Off-Balance Sheet Arrangements

We had no material off-balance sheet arrangements as of March 31, 2007.

Contractual Obligations

The following table summarizes our principal contractual obligations as of March 31, 2007 that have changed significantly since December 31, 2006 and the effects such obligations are expected to have on our liquidity and cash flow in future periods. Contractual obligations that were presented in our Annual Report on Form 10-K/A for the year ended December 31, 2006 but omitted in the table below represent those that have not changed significantly since that date.

| Contractual Obligations | Total | Payments Due by Period | | | Thereafter |
|-------------------------------|------------|------------------------|-----------|-----------|------------|
| | | 2007 | 2008-2009 | 2010-2011 | |
| | | (in thousands) | | | |
| Long-term debt obligations(1) | \$ 159,008 | \$ 8,876 | \$ 132 | \$ | \$ 150,000 |

(1) Long-term debt obligations decreased by \$43.0 million since December 31, 2006 primarily due to our repayment of borrowings under the lines of credit of our primary senior credit facility during the three months ended March 31, 2007.

As of March 31, 2007, we had contingent consideration obligations related to our acquisitions of Instant, First Check, Binax and Clondiag. The contingent considerations will be accounted for as increases in the aggregate purchase prices if and when the contingencies occur.

With respect to Instant, the terms of the acquisition agreement provide for \$16.6 million of contingent consideration payable in cash or cash and stock to acquire the remaining 25% ownership interest in Instant. The seller, who is now an employee of Instant, has the option, but is not obligated, to sell his remaining 25% during the four-year period commencing April 1, 2008 and ending March 31, 2012. The option is contingent upon the business meeting

certain revenue and gross profit targets or may be triggered should the seller be terminated as an employee, without cause. The option shall terminate if not exercised during the period mentioned above. Furthermore, we have the option, but not an obligation, to acquire the remaining 25% from the seller on or before March 31, 2012 for \$24.6 million in cash or cash and stock. If the seller is no longer an employee of the company at the time of exercise, the full consideration shall be payable in cash. The option shall terminate if not exercised during the period mentioned above.

With respect to First Check, we will pay an earn-out to First Check equal to the incremental revenue growth of the acquired products for 2007 and for the first nine months of 2008, as compared to the immediately preceding comparable periods.

With respect to Binax, the terms of the acquisition agreement provide for \$11.0 million of contingent cash consideration payable to the Binax shareholders upon the successful completion of certain new product developments during the five years following the acquisition.

With respect to Clondiag, the terms of the acquisition agreement provide for \$8.9 million of contingent consideration, consisting of 224,316 shares of our common stock and approximately \$3.0 million of cash or stock in the event that four specified products are developed on Clondiag's platform technology during the three years following the acquisition date.

Table of Contents**Critical Accounting Policies**

The consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q are prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The accounting policies discussed below are considered by our management and our audit committee to be critical to an understanding of our financial statements because their application depends on management's judgment, with financial reporting results relying on estimates and assumptions about the effect of matters that are inherently uncertain. Specific risks for these critical accounting policies are described in the following paragraphs. For all of these policies, management cautions that future events rarely develop exactly as forecast and the best estimates routinely require adjustment. In addition, the notes to our audited consolidated financial statements for the year ended December 31, 2006 included in our Annual Report on Form 10-K/A include a comprehensive summary of the significant accounting policies and methods used in the preparation of our consolidated financial statements.

Revenue Recognition

We primarily recognize revenue when the following four basic criteria have been met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed and determinable; and (4) collection is reasonably assured.

The majority of our revenue is derived from product sales. We recognize revenue upon title transfer of the products to third-party customers, less a reserve for estimated product returns and allowances. Determination of the reserve for estimated product returns and allowances is based on our management's analyses and judgments regarding certain conditions, as discussed below in the critical accounting policy *Use of Estimates for Sales Returns and Other Allowances and Allowance for Doubtful Accounts*. Should future changes in conditions prove management's conclusions and judgments on previous analyses to be incorrect, revenue recognized for any reporting period could be adversely affected.

In connection with the acquisition of the Abbott rapid diagnostics business in September 2003 and the Determine business in June 2005 from Abbott Laboratories, we entered into a transition services agreement with Abbott, whereby Abbott would continue to distribute certain of the acquired products for a period of up to 18 months following each acquisition, subject to certain extensions. During the transition period, we recognized revenue on sales of the products when title transferred from Abbott to third party customers.

We also receive license and royalty revenue from agreements with third-party licensees. Revenue from fixed fee license and royalty agreements are recognized on a straight-line basis over the obligation period of the related license agreements. License and royalty fees that the licensees calculate based on their sales, which we have the right to audit under most of our agreements, are generally recognized upon receipt of the license or royalty payments unless we are able to reasonably estimate the fees as they are earned. License and royalty fees that are determinable prior to the receipt thereof are recognized in the period they are earned.

Use of Estimates for Sales Returns and Other Allowances and Allowance for Doubtful Accounts

Certain sales arrangements require us to accept product returns. From time to time, we also enter into sales incentive arrangements with our retail customers, which generally reduce the sale prices of our products. As a result, we must establish allowances for potential future product returns and claims resulting from our sales incentive arrangements against product revenue recognized in any reporting period. Calculation of these allowances requires significant judgments and estimates. When evaluating the adequacy of the sales returns and other allowances, our management analyzes historical returns, current economic trends, and changes in customer and consumer demand and acceptance of our products. When such analysis is not available and a right of return exists the Company records revenue when the right of return is no longer applicable. Material differences in the amount and timing of our product revenue for any reporting period may result if changes in conditions arise that would require management to make different judgments or utilize different estimates.

Our total provision for sales returns and other allowances related to sales incentive arrangements amounted to \$11.9 million and \$14.1 million, or 7% and 10%, respectively, of product sales for the three months ended March 31, 2007 and 2006, respectively, which have been recorded against product sales to derive our net product sales.

Similarly, our management must make estimates regarding uncollectible accounts receivable balances. When evaluating the adequacy of the allowance for doubtful accounts, management analyzes specific accounts receivable

balances, historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in our customer payment terms and patterns. Our accounts receivable balance was \$99.9 million and \$100.0 million, net of allowances for doubtful accounts of \$8.9 million and \$8.4 million, as of March 31, 2007 and December 31, 2006, respectively.

Valuation of Inventories

We state our inventories at the lower of the actual cost to purchase or manufacture the inventory or the estimated current market value of the inventory. In addition, we periodically review the inventory quantities on hand and record a provision for excess and

Table of Contents

obsolete inventory. This provision reduces the carrying value of our inventory and is calculated based primarily upon factors such as forecasts of our customers' demands, shelf lives of our products in inventory, loss of customers, manufacturing lead times and, less commonly, decisions to withdraw our products from the market. Evaluating these factors, particularly forecasting our customers' demands, requires management to make assumptions and estimates. Actual product sales may prove our forecasts to be inaccurate, in which case we may have underestimated or overestimated the provision required for excess and obsolete inventory. If, in future periods, our inventory is determined to be overvalued, we would be required to recognize the excess value as a charge to our cost of sales at the time of such determination. Likewise, if, in future periods, our inventory is determined to be undervalued, we would have over-reported our cost of sales, or understated our earnings, at the time we recorded the excess and obsolete provision. Our inventory balance was \$87.3 million and \$78.3 million, net of a provision for excess and obsolete inventory of \$4.3 million and \$8.2 million, as of March 31, 2007 and December 31, 2006, respectively.

Valuation of Goodwill and Other Long-Lived and Intangible Assets

Our long-lived assets include: (1) property, plant and equipment, (2) goodwill and (3) other intangible assets. As of March 31, 2007, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were \$81.3 million, \$489.4 million and \$261.3 million, respectively.

Goodwill and other intangible assets are initially created as a result of business combinations or acquisitions of intellectual property. The values we record for goodwill and other intangible assets represent fair values calculated by accepted valuation methods. Such valuations require us to provide significant estimates and assumptions which are derived from information obtained from the management of the acquired businesses and our business plans for the acquired businesses or intellectual property. Critical estimates and assumptions used in the initial valuation of goodwill and other intangible assets include, but are not limited to: (1) future expected cash flows from product sales, customer contracts and acquired developed technologies and patents, (2) expected costs to complete any in-process research and development projects and commercialize viable products and estimated cash flows from sales of such products, (3) the acquired companies' brand awareness and market position, (4) assumptions about the period of time over which we will continue to use the acquired brand and (5) discount rates. These estimates and assumptions may be incomplete or inaccurate because unanticipated events and circumstances may occur. If estimates and assumptions used to initially value goodwill and intangible assets prove to be inaccurate, ongoing reviews of the carrying values of such goodwill and intangible assets, as discussed below, may indicate impairment which will require us to record an impairment charge in the period in which we identify the impairment.

Where we believe that property, plant and equipment and intangible assets have finite lives, we depreciate and amortize those assets over their estimated useful lives. For purposes of determining whether there are any impairment losses, as further discussed below, our management has historically examined the carrying value of our identifiable long-lived tangible and intangible assets and goodwill, including their useful lives where we believe such assets have finite lives, when indicators of impairment are present. In addition, Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets*, requires that impairment reviews be performed on the carrying values of all goodwill on at least an annual basis. For all long-lived tangible and intangible assets and goodwill, if an impairment loss is identified based on the fair value of the asset, as compared to the carrying value of the asset, such loss would be charged to expense in the period we identify the impairment. Furthermore, if our review of the carrying values of the long-lived tangible and intangible assets with finite lives indicates impairment of such assets, we may determine that shorter estimated useful lives are more appropriate. In that event, we will be required to record additional depreciation and amortization in future periods, which will reduce our earnings.

Valuation of Goodwill

We have goodwill balances related to our consumer diagnostics and professional diagnostics reporting segments, which amounted to \$97.3 million and \$392.1 million, respectively, as of March 31, 2007. As of September 30, 2006, we performed our annual impairment review on the carrying values of such goodwill using the discounted cash flows approach. Based upon this review, we do not believe that the goodwill related to our consumer diagnostics and professional diagnostics reporting units were impaired. Because future cash flows and operating results used in the impairment review are based on management's projections and assumptions, future events can cause such projections to differ from those used at September 30, 2006, which could lead to significant impairment charges of goodwill in the

future. No events or circumstances have occurred since our review as of September 30, 2006, that would require us to reassess whether the carrying values of our goodwill have been impaired.

Valuation of Other Long-Lived Tangible and Intangible Assets

Factors we generally consider important which could trigger an impairment review on the carrying value of other long-lived tangible and intangible assets include the following: (1) significant underperformance relative to expected historical or projected future operating results; (2) significant changes in the manner of our use of acquired assets or the strategy for our overall business; (3) underutilization of our tangible assets; (4) discontinuance of product lines by ourselves or our customers; (5) significant negative

Table of Contents

industry or economic trends; (6) significant decline in our stock price for a sustained period; (7) significant decline in our market capitalization relative to net book value; and (8) goodwill impairment identified during an impairment review under SFAS No. 142. Although we believe that the carrying value of our long-lived tangible and intangible assets was realizable as of March 31, 2007, future events could cause us to conclude otherwise.

Stock-Based Compensation

As of January 1, 2006, we account for stock-based compensation in accordance with SFAS No. 123-R, *Share-Based Payment*. Under the fair value recognition provisions of this statement, share-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the vesting period. Determining the fair value of share-based awards at the grant date requires judgment, including estimating our stock price volatility and employee stock option exercise behaviors. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations could be materially impacted.

Our expected volatility is based upon the historical volatility of our stock. We have chosen to utilize the simplified method to calculate the expected life of options which averages an award's weighted average vesting period and its contractual term. As stock-based compensation expense is recognized in our consolidated statement of operations is based on awards ultimately expected to vest, the amount of expense has been reduced for estimated forfeitures. SFAS No. 123-R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. If factors change and we employ different assumptions in the application of SFAS No. 123-R, the compensation expense that we record in future periods may differ significantly from what we have recorded in the current period.

Accounting for Income Taxes

As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our actual current tax exposure and assessing temporary differences resulting from differing treatment of items, such as reserves and accruals and lives assigned to long-lived and intangible assets, for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered through future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within our tax provision.

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a valuation allowance of \$107.6 million as of December 31, 2006 due to uncertainties related to the future benefits, if any, from our deferred tax assets related primarily to our U.S. businesses and certain foreign net operating losses and tax credits. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to establish an additional valuation allowance or reduce our current valuation allowance which could materially impact our tax provision.

On January 1, 2007 we adopted Financial Accounting Standards Board (FASB) Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement 109*. In accordance with FIN 48, we established reserves for tax uncertainties that reflect the use of the comprehensive model for the recognition and measurement of uncertain tax positions. We are currently undergoing routine tax examinations by various state and foreign jurisdictions. Tax authorities periodically challenge certain transactions and deductions we reported on our income tax returns. We do not expect the outcome of these examinations, either individually or in the aggregate, to have a material adverse effect on our financial position, results of operations, or cash flows.

Prior to January 1, 2007 in accordance with SFAS No. 109, *Accounting for Income Taxes*, and SFAS No. 5, *Accounting for Contingencies*, we established reserves for tax contingencies that reflect our best estimate of the transactions and deductions that we may be unable to sustain or that we could be willing to concede as part of a broader tax settlement.

It has been our practice to permanently reinvest all foreign earnings into foreign operations and we currently expect to continue to reinvest foreign earnings permanently into our foreign operations. Should we plan to repatriate any

foreign earnings in the future, we will be required to establish an income tax expense and related tax liability on such earnings.

Loss Contingencies

In the section of our Annual Report on Form 10-K/A for the year ended December 31, 2006, titled Item 3. Legal Proceedings, we have reported on material legal proceedings. In addition, because of the nature of our business, we may from time to time be subject to commercial disputes, consumer product claims or various other lawsuits arising in the ordinary course of our business, and

Table of Contents

we expect this will continue to be the case in the future. These lawsuits generally seek damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, which can be expensive and can result in counterclaims against us.

We do not accrue for potential losses on legal proceedings where our company is the defendant when we are not able to reasonably estimate our potential liability, if any, due to uncertainty as to the nature, extent and validity of the claims against us, uncertainty as to the nature and extent of the damages or other relief sought by the plaintiff and the complexity of the issues involved. Our potential liability, if any, in a particular case may become reasonably estimable and probable as the case progresses, in which case we will begin accruing for the expected loss.

Recent Accounting Pronouncements*Recently Issued Accounting Standards*

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application is encouraged. We continue to evaluate the impact that the adoption of SFAS No. 157 will have, if any, on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB No 115*. This Statement provides companies with an option to measure, at specified election dates, many financial instruments and certain other items at fair value that are not currently measured at fair value. The standard also establishes presentation and disclosure requirements designed to facilitate comparison between entities that choose different measurement attributes for similar types of assets and liabilities. If the fair value option is elected, the effect of the first remeasurement to fair value is reported as a cumulative effect adjustment to the opening balance of retained earnings. The statement is to be applied prospectively upon adoption. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We plan to adopt SFAS No. 159 as of January 1, 2008, and are currently evaluating the impact of SFAS No. 159 on our results of operations or financial position.

Recently Adopted Accounting Standards

We adopted FIN 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement 109* on January 1, 2007. FIN 48 clarifies the accounting and reporting for uncertainties in income tax law. This Interpretation prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. See Note 6 for information pertaining to the effects of adoption on our consolidated balance sheet.

In February 2006, the FASB issued SFAS No. 155, *Accounting for Certain Hybrid Financial Instruments*, which amends SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* and SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. SFAS No. 155 simplifies the accounting for certain derivatives embedded in other financial instruments by allowing them to be accounted for as a whole if the holder elects to account for the whole instrument on a fair value basis. SFAS No. 155 also clarifies and amends certain other provisions of SFAS No. 133 and SFAS No. 140. SFAS No. 155 is effective for all financial instruments acquired, issued or subject to a remeasurement event occurring in fiscal years beginning after September 15, 2006. The adoption of SFAS No. 155 did not have any impact on our financial position, results of operations or cash flows.

In June 2006, the FASB ratified the consensus on Emerging Issue Task Force (EITF) Issue No. 06-03, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement*. The scope of EITF Issue No. 06-03 includes any tax assessed by a governmental authority that is directly imposed on a revenue-producing transaction between a seller and a customer and may include, but is not limited to, sales, use, value added, Universal Service Fund (USF) contributions and some excise taxes. The Task Force affirmed its

conclusion that entities should present these taxes in the income statement on either a gross or a net basis, based on their accounting policy, which should be disclosed pursuant to Accounting Principles Board (APB) Opinion No. 22, *Disclosure of Accounting Policies*. If such taxes are significant, and are presented on a gross basis, the amounts of those taxes should be disclosed. The consensus on Issue No. 06-03 will be effective for interim and annual reporting periods beginning after December 15, 2006. As required by EITF 06-03, we adopted this new accounting standard for the interim period beginning January 1, 2007. The adoption of EITF 06-03 did not have any impact on our financial position, results of operations or cash flows.

Table of Contents

In December 2006, the FASB issued FASB Staff Position (FSP) No. EITF 00-19-2, *Accounting for Registration Payment Arrangements*. This FSP specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5, *Accounting for Contingencies*. The guidance in this FSP amends FASB Statement No. 133, *Accounting for Derivative Financial Instruments and Hedging Activities*, and No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* and FIN 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* to include scope exceptions for registration payment arrangements. This FSP is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issuance of this FSP. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of this FSP, this guidance shall be effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. As required by EITF 00-19-2, we adopted this new accounting standard on January 1, 2007. The adoption of EITF 00-19-2 did not have any impact on our financial position, results of operations or cash flows.

SPECIAL STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, continue or similar words. You should read statements that contain these words carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. There may be events in the future that we are not able to predict accurately or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. We caution investors that all forward-looking statements involve risks and uncertainties, and actual results may differ materially from those we discuss in this report. These differences may be the result of various factors, including those factors described in Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K for the fiscal year ending December 31, 2006, as amended, and other risk factors identified herein or from time to time in our periodic filings with the SEC. Some important factors that could cause our actual results to differ materially from those projected in any such forward-looking statements are as follows:

economic factors, including inflation and fluctuations in interest rates and foreign currency exchange rates, and the potential effect of such fluctuations on revenues, expenses and resulting margins;

competitive factors, including technological advances achieved and patents attained by competitors and generic competition;

domestic and foreign healthcare changes resulting in pricing pressures, including the continued consolidation among healthcare providers, trends toward managed care and healthcare cost containment and government laws and regulations relating to sales and promotion, reimbursement and pricing generally;

government laws and regulations affecting domestic and foreign operations, including those relating to trade, monetary and fiscal policies, taxes, price controls, regulatory approval of new products and licensing;

manufacturing interruptions, delays or capacity constraints or lack of availability of alternative sources for components for our products, including our ability to successfully maintain relationships with suppliers, or to put in place alternative suppliers on terms that are acceptable to us;

difficulties inherent in product development, including the potential inability to successfully continue technological innovation, complete clinical trials, obtain regulatory approvals or clearances in the United States and abroad, gain and maintain market approval or clearance of products and the possibility of encountering

infringement claims by competitors with respect to patent or other intellectual property rights which can preclude or delay commercialization of a product;

significant litigation adverse to us, including product liability claims, patent infringement claims and antitrust claims;

our ability to comply with regulatory requirements, including the outcome of the Securities and Exchange Commission's, or the SEC's, ongoing investigation into the revenue recognition issues at our Wampole subsidiary disclosed in June 2005 and the ongoing inquiry by the Federal Trade Commission, or the FTC, of our acquisition of the Innovacon business;

product efficacy or safety concerns resulting in product recalls or declining sales;

the impact of business combinations, including acquisitions and divestitures;

our ability to consummate our pending joint venture transaction with The Procter & Gamble Company, or P&G, and the impact of the joint venture on our future financial performance;

Table of Contents

our ability to successfully put to use the proceeds we expect to receive in connection with the formation of the pending joint venture with P&G;

our ability to satisfy the financial covenants and other conditions contained in the agreements governing our indebtedness;

our ability to obtain required financing on terms that are acceptable to us;

our ability to come to an agreement to acquire Biosite, and our ability to consummate any such agreement;

a significant increase in indebtedness if we are successful in acquiring Biosite; and

the issuance of new or revised accounting standards by the American Institute of Certified Public Accountants, the Financial Accounting Standards Board, the Public Company Accounting Oversight Board or the SEC.

The foregoing list sets forth many, but not all, of the factors that could impact upon our ability to achieve results described in any forward-looking statements. Readers should not place undue reliance on our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described above and elsewhere in this report could harm our business, prospects, operating results and financial condition. We do not undertake any obligation to update any forward-looking statements as a result of future events or developments.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The following discussion about our market risk disclosures involves forward-looking statements. Actual results could differ materially from those discussed in the forward-looking statements. We are exposed to market risk related to changes in interest rates and foreign currency exchange rates. We do not use derivative financial instruments for speculative or trading purposes.

Interest Rate Risk

We are exposed to market risk from changes in interest rates primarily through our investing and financing activities. In addition, our ability to finance future acquisition transactions or fund working capital requirements may be impacted if we are not able to obtain appropriate financing at acceptable rates.

Our investing strategy, to manage interest rate exposure, is to invest in short-term, highly liquid investments. Our investment policy also requires investment in approved instruments with an initial maximum allowable maturity of eighteen months and an average maturity of our portfolio that should not exceed six months, with at least \$500,000 cash available at all times. Currently, our short-term investments are in money market funds with original maturities of 90 days or less. At March 31, 2007, our short-term investments approximated market value.

At March 31, 2007, we had revolving lines of credit available to us of up to \$110.0 million in the aggregate under our primary senior credit facility, against which no balance was outstanding. Borrowings under the revolving lines of credit bear interest at either (i) the London Interbank Offered Rate, or LIBOR, as defined in the credit agreement, plus applicable margins or, at our option, (ii) a floating Index Rate, as defined in the agreement, plus applicable margins. Applicable margins if we choose to use the LIBOR or the Index Rate can range from 2.75% to 3.75% or 1.50% to 2.50%, respectively, depending on the quarterly adjustments that are based on our consolidated financial performance.

Foreign Currency Risk

We face exposure to movements in foreign currency exchange rates whenever we, or any of our subsidiaries, enter into transactions with third parties that are denominated in currencies other than our, or its, functional currency. Intercompany transactions between entities that use different functional currencies also expose us to foreign currency risk. During the three months ended March 31, 2007, the net impact of foreign currency changes on transactions was a loss of \$0.5 million. Generally, we do not use derivative financial instruments or other financial instruments with original maturities in excess of three months to hedge such economic exposures.

Gross margins of products we manufacture at our European plants and sell in U.S. Dollar are also affected by foreign currency exchange rate movements. Our gross margin on total net product sales was 49.4% for the three

months ended March 31, 2007. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during the three months ended March 31, 2007, our gross margin on total net product sales would have been 49.5%, 50.1%, and 50.8%, respectively.

In addition, because a substantial portion of our earnings is generated by our foreign subsidiaries, whose functional currencies are other than the U.S. Dollar (in which we report our consolidated financial results), our earnings could be materially impacted by movements in foreign currency exchange rates upon the translation of the earnings of such subsidiaries into the U.S. Dollar. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual average exchange rates used to translate the financial results

Table of Contents

of our foreign subsidiaries, our net revenue and net loss would have been lower by approximately the following amounts (in thousands):

| If, during the three months ended March 31, 2007, the U.S. dollar was stronger by: | Approximate decrease in net revenue | Approximate decrease in net income |
|---|--|---|
| 1% | \$ 523 | \$ 35 |
| 5% | \$ 2,617 | \$ 176 |
| 10% | \$ 5,234 | \$ 352 |

ITEM 4. CONTROLS AND PROCEDURES*Evaluation of Disclosure Controls and Procedures*

Our management evaluated, with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), the effectiveness of the design and operation of our company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our management, including the CEO and CFO, concluded that our company's disclosure controls and procedures were effective at that time. We and our management understand nonetheless that controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. In reaching their conclusions stated above regarding the effectiveness of our disclosure controls and procedures, our CEO and CFO concluded that such disclosure controls and procedures were effective as of such date at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION**Item 1A. Risk Factors**

On May 9, 2007, we made a binding offer to acquire by way of a cash tender offer all of the outstanding common stock of Biosite that we do not already own (we currently own approximately 4.6% of the outstanding stock of Biosite) for \$92.50 per share. Under the new offer, in the event that we enter into a definitive agreement with Biosite, we would commence an up-front tender offer to acquire all of Biosite's outstanding shares at a price of \$92.50 per share, payable in cash, and complete a follow-on merger. Our proposal follows action taken by Beckman Coulter and Biosite to amend the terms of their previously signed merger agreement, as well as Beckman Coulter's tender offer, to provide for a purchase price of \$90.00 per share of Biosite common stock (this matched our previous offer to acquire Biosite for \$90.00 per share). Under the Beckman Coulter merger agreement, if Biosite's board of directors determines that our acquisition proposal constitutes a superior proposal (as defined in the Beckman Coulter merger agreement) to Beckman Coulter's existing agreement to acquire Biosite at a price of \$90.00 per share, Beckman Coulter must be given three (3) business days to make a proposal to Biosite that Biosite's board of directors determines is at least as favorable to its shareholders as our acquisition proposal. In the event such a proposal is not made, or if made, Biosite's board of directors does not determine that Beckman Coulter's proposal is at least as favorable as our proposal, Biosite may terminate the Beckman Coulter merger agreement. If Biosite terminates the Beckman Coulter merger agreement in these circumstances in order to enter into our proposed merger agreement, Biosite will be obligated to pay Beckman Coulter a \$54.0 million termination fee. Under our proposed merger agreement we would reimburse Biosite for this fee.

There is no assurance that Biosite's board of directors will deem our offer superior to Beckman Coulter's offer, or that Biosite will enter into a merger agreement with us, and any merger agreed to may not ultimately be consummated if various closing conditions are not met. If we do ultimately succeed in acquiring Biosite, we will significantly

increase our indebtedness. The commitment letters received by us in connection with the proposed acquisition of Biosite contemplate a total of \$1.60 billion in additional indebtedness and available credit. In addition, we may not realize all of the benefits of the acquisition that we expect.

The risks related to significant indebtedness, acquisitions and the integration of acquired businesses, which are applicable to the proposed acquisition of Biosite, also impact our business generally and are discussed in Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K, as amended, for the fiscal year ending December 31, 2006.

Otherwise, there have been no material changes from the Risk Factors previously disclosed in Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K for the fiscal year ending December 31, 2006, as amended.

ITEM 6. EXHIBITS

Exhibits:

| Exhibit No. | Description |
|--------------------|--|
| **2.1 | Stock Purchase Agreement, as of March 12, 2007, by and among Inverness Medical Innovations, Inc., James T. Ramsey, Gerald T. Ramsey, Tara Ramsey, Edward Bennett, and Instant Technologies, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, event date March 12, 2007, filed on March 16, 2007). |
| *4.1 | Sixth Supplemental Indenture, dated as of March 14, 2007, among Inverness Medical Innovations, Inc., the Guarantors, First Check Diagnostics Corp. and U.S. Bank Trust National Association, as Trustee. |
| *4.2 | Seventh Supplemental Indenture, dated as of May 1, 2007, among Inverness Medical Innovations, Inc., the Guarantors, Instant Technologies, Inc. and U.S. Bank Trust National Association, as Trustee. |

Table of Contents

| Exhibit No. | Description |
|---------------------|--|
| **10.1 | Ninth Amendment and Consent to Third Amended and Restated Credit Agreement, dated as of November 10, 2006, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005 (as amended, supplemented or otherwise modified from time to time), by and among General Electric Capital Corporation, as Agent, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC and Inverness Medical (UK) Holdings Limited, as Borrowers, the other Credit Parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, co-syndication agent and lender, UBS Securities LLC, as co-syndication agent, and the Lenders signatory thereto from time to time (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2006). |
| *31.1 | Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| *31.2 | Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| *32.1 | Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| * Filed herewith | |
| ** Previously filed | |

Table of Contents

SIGNATURE

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.

INVERNESS MEDICAL INNOVATIONS,
INC.

Date: May 10, 2007

/s/ DAVID TEITEL
David Teitel
Chief Financial Officer and an authorized
officer

39