

INVERNESS MEDICAL INNOVATIONS INC

Form 10-Q

November 08, 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 September 30, 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 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 November 2, 2007 was 55,502,671.

INVERNESS MEDICAL INNOVATIONS, INC.
REPORT ON FORM 10-Q
For the Quarterly Period Ended September 30, 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 42, 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:</u> | |
| <u>a) Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2007 and 2006</u> | 3 |
| <u>b) Consolidated Balance Sheets as of September 30, 2007 and December 31, 2006</u> | 4 |
| <u>c) Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 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> | 43 |
| <u>Item 4. Controls and Procedures</u> | 45 |
| <u>PART II. OTHER INFORMATION</u> | |
| <u>Item 1A. Risk Factors</u> | 45 |
| <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u> | 45 |
| <u>Item 6. Exhibits</u> | 46 |

SIGNATURE

47

EX-10.1 Lease Agreement between Cholestech Corporation and the BIV Group

EX-10.2 Lease Agreement Addendum No. One by and between Cholestech Corporation and BIV Group

EX-31.1 Certification by Chief Executive Officer Pursuant to Section 302

EX-31.2 Certification by Chief Financial Officer Pursuant to Section 302

EX-32.1 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906

2

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 | | Nine Months Ended | |
|--|---------------------------|-------------|--------------------------|-------------|
| | September 30, | | September 30, | |
| | 2007 | 2006 | 2007 | 2006 |
| Net product sales | \$ 228,568 | \$ 140,896 | \$ 534,521 | \$ 400,246 |
| License and royalty revenue | 9,068 | 4,016 | 17,059 | 12,200 |
| Net revenue | 237,636 | 144,912 | 551,580 | 412,446 |
| Cost of sales | 127,338 | 83,767 | 296,604 | 250,551 |
| Gross profit | 110,298 | 61,145 | 254,976 | 161,895 |
| Operating expenses: | | | | |
| Research and development (Note 12) | 20,530 | 11,065 | 44,649 | 34,789 |
| Purchase of in-process research and development (Note 13) | 169,000 | 4,960 | 169,000 | 4,960 |
| Sales and marketing | 48,536 | 25,986 | 104,847 | 69,498 |
| General and administrative | 28,707 | 18,090 | 119,161 | 51,606 |
| Loss on dispositions, net | | | | 3,191 |
| Operating (loss) income | (156,475) | 1,044 | (182,681) | (2,149) |
| Interest expense, including amortization of original issue discounts and write-off of deferred financing costs (Note 17) | (29,041) | (8,193) | (56,238) | (20,796) |
| Other income (expense), net | 2,143 | (1,158) | 8,822 | 3,690 |
| Loss before (benefit) provision for income taxes | (183,373) | (8,307) | (230,097) | (19,255) |
| (Benefit) provision for income taxes | (1,645) | 1,621 | 1,550 | 3,884 |
| Equity earnings of unconsolidated entities, net of tax (Note 14) | 1,116 | 245 | 2,666 | 270 |
| Net loss | \$ (180,612) | \$ (9,683) | \$ (228,981) | \$ (22,869) |
| Net loss per common share basic and diluted (Note 6) | \$ (3.74) | \$ (0.27) | \$ (4.89) | \$ (0.70) |
| Weighted average common shares basic and diluted (Note 6) | 48,256 | 35,396 | 46,787 | 32,498 |

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

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except par value)

| | September 30, 2007 (unaudited) | December 31, 2006 |
|--|---|----------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 153,345 | \$ 71,104 |
| Marketable securities | 2,734 | |
| Accounts receivable, net of allowances of \$8,360 at September 30, 2007 and \$8,401 at December 31, 2006 | 122,808 | 100,388 |
| Inventories, net | 136,487 | 78,322 |
| Deferred tax assets | 24,152 | 5,332 |
| Income taxes receivable | 28,482 | 3,014 |
| Prepaid expenses and other current assets | 64,602 | 17,384 |
| Total current assets | 532,610 | 275,544 |
| Property, plant and equipment, net | 243,050 | 82,312 |
| Goodwill | 1,359,951 | 439,369 |
| Other intangible assets with indefinite lives | 42,937 | 68,107 |
| Core technology and patents, net | 403,281 | 87,732 |
| Other intangible assets, net | 655,465 | 83,794 |
| Deferred financing costs, net and other non-current assets | 50,408 | 13,218 |
| Investments in unconsolidated entities | 85,025 | 22,936 |
| Marketable securities | | 12,681 |
| Deferred tax assets | 118,814 | 78 |
| Total assets | \$ 3,491,541 | \$ 1,085,771 |
| LIABILITIES AND STOCKHOLDERS EQUITY | | |
| Current liabilities: | | |
| Current portion of long-term debt | \$ 8,389 | \$ 7,504 |
| Current portion of capital lease obligations | 583 | 584 |
| Accounts payable | 57,207 | 46,342 |
| Accrued expenses and other current liabilities | 151,274 | 87,801 |
| Total current liabilities | 217,453 | 142,231 |
| Long-term liabilities: | | |
| Long-term debt, net of current portion | 1,340,975 | 194,473 |
| Capital lease obligations, net of current portion | 206 | 415 |
| Deferred tax liabilities | 306,123 | 23,984 |
| Deferred gain on joint venture | 302,514 | |
| Other long-term liabilities | 17,221 | 10,530 |
| Total long-term liabilities | 1,967,039 | 229,402 |

Commitments and contingencies (Note 21)

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: 55,150 shares at September 30, 2007 and 39,215 shares at December 31, 2006 | 55 | 39 |
| Additional paid-in capital | 1,637,692 | 826,987 |
| Accumulated deficit | (356,050) | (127,069) |
| Accumulated other comprehensive income | 25,352 | 14,181 |
| Total stockholders equity | 1,307,049 | 714,138 |
| Total liabilities and stockholders equity | \$ 3,491,541 | \$ 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)

| | Nine Months Ended | |
|---|--------------------------|------------------|
| | September 30, | |
| | 2007 | 2006 |
| Cash Flows from Operating Activities: | | |
| Net loss | \$ (228,981) | \$ (22,869) |
| Adjustments to reconcile net loss to net cash provided by operating activities: | | |
| Interest expense related to amortization of non-cash original issue discount and amortization and write-off of deferred financing costs | 9,549 | 3,252 |
| Non-cash income related to currency hedge | | (217) |
| Non-cash stock-based compensation expense | 46,926 | 3,872 |
| Charge for in-process research and development | 169,000 | 4,960 |
| Loss on sale of fixed assets | 156 | |
| Interest in minority investments | (1,264) | |
| Depreciation and amortization | 61,604 | 29,213 |
| Deferred and other non-cash income taxes | 7,046 | 1,860 |
| Impairment of long-lived assets | | 9,143 |
| Other non-cash items | 31 | (1,517) |
| Changes in assets and liabilities, net of acquisitions: | | |
| Accounts receivable, net | 41,684 | (25,019) |
| Inventories, net | (7,104) | (8,607) |
| Prepaid expenses and other current assets | (21,851) | 3,067 |
| Accounts payable | (6,735) | 16,202 |
| Accrued expenses and other current liabilities | (30,734) | (6,681) |
| Other non-current liabilities | (5,302) | 224 |
| Net cash provided by operating activities | 34,025 | 6,883 |
| Cash Flows from Investing Activities: | | |
| Purchases of property, plant and equipment | (21,711) | (13,557) |
| Proceeds from sale of equipment | 170 | 2,217 |
| Cash paid for acquisitions and transactional costs, net of cash acquired | (1,590,107) | (124,395) |
| Cash received, net of cash paid, to form joint venture | 324,170 | |
| Cash paid for minority interest investments | (13,446) | |
| Increase in other assets | (29,509) | (2,031) |
| Net cash used in investing activities | (1,330,433) | (137,766) |
| Cash Flows from Financing Activities: | | |
| Cash paid for financing costs | (38,100) | (2,012) |
| Proceeds from issuance of common stock, net of issuance costs | 300,901 | 231,333 |
| Net proceeds (payments) of long-term debt | 1,131,088 | (45,127) |
| Payments on short-term note payable | (22,326) | (22,614) |
| Payments received on note receivable | | 10,665 |
| Tax benefit on exercised stock options | 625 | |

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| | | |
|--|------------|-----------|
| Principal payments of capital lease obligations | (427) | (409) |
| Net cash provided by financing activities | 1,371,761 | 171,836 |
| Foreign exchange effect on cash and cash equivalents | 6,888 | (651) |
| Net increase in cash and cash equivalents | 82,241 | 40,302 |
| Cash and cash equivalents, beginning of period | 71,104 | 34,270 |
| Cash and cash equivalents, end of period | \$ 153,345 | \$ 74,572 |
| Supplemental Disclosure of Non-cash Activities: | | |
| Fair value of stock issued for acquisitions | \$ 357,346 | \$ 68,915 |
| Fair value associated with Biosite and Cholestech employee stock options assumed | \$ 86,162 | \$ |

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 September 30, 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):

| | September 30, 2007 | December 31, 2006 |
|-----------------|-------------------------------|------------------------------|
| Raw materials | \$ 42,036 | \$ 29,372 |
| Work-in-process | 38,406 | 19,080 |
| Finished goods | 56,045 | 29,870 |
| | \$ 136,487 | \$ 78,322 |

(4) Income Tax Receivable

Income tax receivable at September 30, 2007 was \$28.5 million. This income tax receivable is primarily related to a U.S. tax loss of Biosite Incorporated (Biosite). This tax loss will generate refunds of 2007 state income taxes paid as of September 30, 2007 and tax refunds for 2004, 2005 and 2006 federal tax carryback claims.

(5) 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.

Table of Contents

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

In accordance with SFAS No. 123-R, as of September 30, 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 three and nine months ended September 30, 2007 and 2006 and the unvested portion of previous stock option grants which vested during the first nine months of 2007 and 2006. Stock-based compensation expense in the amount of \$3.3 million (\$2.3 million, net of tax) and \$52.2 million (\$49.0 million, net of tax) and \$1.3 million (\$1.3 million, net of tax) and \$3.9 million (\$3.5 million, net of tax) was reflected in the consolidated statement of operations for the three and nine months ended September 30, 2007 and 2006, respectively, as follows (in thousands):

| | Three Months Ended | | Nine months ended | |
|----------------------------|---------------------------|-----------------|--------------------------|-----------------|
| | September 30, | | September 30, | |
| | 2007 | 2006 | 2007 | 2006 |
| Cost of sales | \$ 119 | \$ 89 | \$ 317 | \$ 284 |
| Research and development | 612 | 301 | 1,301 | 858 |
| Sales and marketing | 351 | 101 | 1,043 | 444 |
| General and administrative | 2,201 | 823 | 49,535 | 2,272 |
| | \$ 3,283 | \$ 1,314 | \$ 52,196 | \$ 3,858 |

Included in the amount above for general and administrative expense for the nine months ended September 30, 2007, is \$45.2 million related to our assumption of Biosite options. The expense relates to the acceleration of unvested Biosite employee options. See Note 10(b) regarding our acquisition of Biosite.

In connection with our acquisition of Cholestech Corporation (Cholestech), we assumed unvested restricted stock awards for which we issued 38,479 restricted shares of our common stock. The expense recognition for such awards is consistent with the treatment of our other stock-based compensation awards as described above. Included in the \$3.3 million and \$52.2 million for the three and nine months ended September 30, 2007, respectively, is \$17,000 related to the vesting of these shares.

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 September 30, 2007 and 2006, there was \$0.3 million and \$0, respectively, of excess tax benefits generated from option exercises. For the nine months ended September 30, 2007 and 2006, there was \$0.6 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 and nine months ended September 30, 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 three and nine months ended September 30, 2007 and 2006 using the Black-Scholes option-pricing model:

| | Three Months Ended | | Nine Months Ended September 30, | | | |
|-------------------------|---------------------------|-------------|--|-------------|-------------|-------------|
| | September 30, | | 2007 | | 2006 | |
| Stock Options: | 2007 | 2006 | 2007 | 2006 | 2007 | 2006 |
| Risk-free interest rate | 4.45% | 4.00% | 4.45% | 5.00% | 4.00% | 4.38% |

| | | | | |
|-------------------------|------------|------------|------------|------------|
| Expected dividend yield | | | | |
| Expected term | 6.25 years | 6.25 years | 6.25 years | 6.25 years |
| Expected volatility | 43.83% | 42% | 43.83% | 42% |

| | Three Months Ended | | Nine Months Ended September 30, | |
|--------------------------------------|---------------------------|-------------|--|-------------|
| | September 30, | | 2007 | |
| Employee Stock Purchase Plan: | 2007 | 2006 | 2007 | 2006 |
| Risk-free interest rate | 4.17 | 4.99% | 4.17% | 4.99% |
| Expected dividend yield | | | | |
| Expected term | 184 days | 184 days | 184 days | 184 days |
| Expected volatility | 69.49% | 33.19% | 69.49% | 33.19% |

A summary of the stock option activity for the nine months ended September 30, 2007 is as follows (in thousands, except exercise price and contractual term):

Table of Contents

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

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic value |
|---|----------------|--|--|--|
| Options outstanding, January 1, 2007 | 3,775 | \$ 21.11 | | |
| Acquired(1) | 2,845 | \$ 26.63 | | |
| Granted | 1,673 | \$ 44.10 | | |
| Exercised | (1,503) | \$ 25.32 | | |
| Canceled/forfeited/expired | (93) | \$ 34.33 | | |
| Options outstanding, September 30, 2007 | 6,697 | \$ 28.07 | 6.60 years | \$ 182,623 |
| Options exercisable, September 30, 2007 | 3,923 | \$ 20.89 | 4.92 years | \$ 135,174 |

(1) Acquired with the acquisitions of Biosite and Cholestech.

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during the nine months ended September 30, 2007 and 2006 was \$21.57 per share and \$12.93 per share, respectively.

The aggregate intrinsic value of stock options exercised during the three and nine months ended September 30, 2007 was \$32.7 million and \$36.5 million, respectively.

Based on equity awards outstanding as of September 30, 2007, there was \$46.4 million of unrecognized compensation costs related to unvested share-based compensation arrangements that are expected to vest. Such costs are expected to be recognized over a weighted average period of 3.14 years.

(6) Net Loss Per Common Share

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|-------------|--|-------------|
| | 2007 | 2006 | 2007 | 2006 |
| Numerator: | | | | |
| Net loss applicable to common stock holders basic and diluted | \$ (180,612) | \$ (9,683) | \$ (228,981) | \$ (22,869) |
| Denominator: | | | | |
| Denominator for basic and diluted net loss per common share weighted average shares | 48,256 | 35,396 | 46,787 | 32,498 |

| | | | | |
|---|-----------|-----------|-----------|-----------|
| Net loss per common share basic and diluted | \$ (3.74) | \$ (0.27) | \$ (4.89) | \$ (0.70) |
|---|-----------|-----------|-----------|-----------|

We had the following potential dilutive securities outstanding on September 30, 2007: options and warrants to purchase an aggregate of 7,002,267 shares of common stock at a weighted average exercise price of \$27.56 per share and 3% convertible notes, convertible at \$52.30, which represent an aggregate 2,868,120 shares, if converted. These potential dilutive securities were not included in the computation of diluted net 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 September 30, 2006: options and warrants to purchase an aggregate of 4,316,816 shares of common stock at a weighted average exercise price of \$19.90 per share. These potential dilutive securities were not included in the computation of diluted net loss per common share because the effect of including such potential dilutive securities would be anti-dilutive.

(7) 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

Table of Contents

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

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. During the nine month period ending September 30, 2007, we increased the liability for income taxes associated with uncertain tax positions by \$6.7 million for a total of \$8.9 million at September 30, 2007. Of the \$6.7 million increase, \$6.3 million is related to Biosite's uncertain tax positions which we assumed at the date of acquisition. These non-current income tax liabilities are recorded in other long-term liabilities in our consolidated balance sheet at September 30, 2007. We anticipate periodic increases to the total amount of unrecognized tax benefits as our business continues to expand.

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 September 30, 2007 was \$0.2 million.

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.

(8) Comprehensive Income (Loss)

We account for comprehensive income (loss) 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 and nine months ended September 30, 2007, we generated a comprehensive loss of \$174.0 million and \$217.8 million, respectively, and for the three and nine months ended September 30, 2006, we generated a comprehensive loss of \$6.4 million and \$17.4 million, respectively.

The consolidated statements of stockholders' equity and comprehensive income (loss) for the year ended December 31, 2006 set forth in our Annual Report on Form 10-K/A for the year ended December 31, 2006 included an incorrect presentation of the adoption of SFAS 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans - An Amendment of FASB Statements No. 87, 88, 106 and 132(R)*. The presentation included a \$3.7 million charge for the impact of the adoption as a component of current-period other comprehensive income rather than displaying the adoption impact as an adjustment to accumulated other comprehensive income.

We will correct the consolidated statement of stockholders' equity and comprehensive income (loss) for the year ended December 31, 2006 in our Annual Report on Form 10-K for the year ending December 31, 2007. The revision will have no impact on net income, total accumulated other comprehensive income, total assets or cash flows for the year ended December 31, 2006.

(9) 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 acquisitions and other investments.

(10) 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

Table of Contents

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

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 are included in our consolidated financial statements of operations after the acquisition date as part of the reporting unit to which it relates. 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 and liabilities assumed 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 EITF 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 Cholestech Corporation

On September 12, 2007, we acquired Cholestech, a publicly-traded leading provider of diagnostic tools and information for immediate risk assessment and therapeutic monitoring of heart disease and inflammatory disorders. The preliminary aggregate purchase price was \$358.7 million, which consisted of 6,840,361 shares of our common stock with an aggregate fair value of \$329.8 million, \$4.3 million for direct acquisition costs, estimated exit costs of \$4.3 million and \$20.3 million of fair value associated with the outstanding fully-vested Cholestech employee stock options which were converted to options to acquire our common stock as part of the transaction. We expect to incur a write-off of in-process research and development (IPR&D) projects that have not yet achieved technological feasibility as of the date of our acquisition of Cholestech and will record the charge through purchase accounting once this amount is determined. We evaluated the business and formulated a restructuring plan which is consistent with our acquisition strategy to realize efficiencies and cost savings. We communicated our plan during the third and fourth quarters of 2007.

The preliminary aggregate purchase price was allocated to the assets acquired and assumed liabilities at the date of acquisition as follows (amounts in thousands, except share data):

| | |
|---------------------------------------|-----------|
| Cash and cash equivalents | \$ 66,521 |
| Accounts receivable | 4,879 |
| Inventories | 10,805 |
| Other current assets | 1,522 |
| Property, plant and equipment | 6,677 |
| Goodwill | 72,279 |
| Trademarks | 20,590 |
| Customer relationships | 99,250 |
| Core technology | 83,810 |
| Internally-developed software | 200 |
| Other non-current assets | 1,047 |
| Accounts payable and accrued expenses | (8,152) |
| Deferred tax liability | (749) |

\$ 358,679

The preliminary aggregate purchase price, as adjusted, was allocated to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. Management has assigned an estimated useful life of 10 years, 26 years, 13 years and 7 years to trademarks, customer relationships, core technology and internally-developed software, respectively, and has recorded these assets in core technology and patents, net and other intangible assets, net in the accompanying consolidated balance sheet at September 30,

10

Table of Contents

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

2007. The excess of the purchase price over the estimated fair value of the assets acquired and liabilities assumed was allocated to goodwill. We expect that substantially all of the amount allocated to goodwill will not be deductible for tax purposes. The allocation of purchase price remains subject to potential adjustments, including adjustments for liabilities associated with certain exit activities and restructuring activities.

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

(b) Acquisition of Biosite Incorporated

On June 29, 2007, we completed our acquisition of Biosite, a publicly-traded global medical diagnostic company utilizing a biotechnology approach to create products for the diagnosis of critical diseases and conditions. The preliminary aggregate purchase price was \$1.8 billion, which consisted of \$1.6 billion in cash, \$68.4 million in estimated direct acquisition costs, \$12.4 million in estimated exit costs and \$77.4 million of fair value associated with the outstanding fully-vested Biosite employee stock options which were converted to options to acquire our common stock as part of the transaction. Furthermore, we evaluated the business and formulated a restructuring plan which is consistent with our acquisition strategy to realize efficiencies and cost savings. We communicated our plan during the third and fourth quarters of 2007.

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

| | |
|---------------------------------------|---------------------|
| Cash and cash equivalents | \$ 174,115 |
| Accounts receivable | 44,386 |
| Inventories | 39,557 |
| Deferred tax asset | 18,691 |
| Other current assets | 40,903 |
| Property, plant and equipment | 147,104 |
| Goodwill | 727,767 |
| Trademarks | 78,100 |
| Customer relationships | 348,100 |
| Core technology | 175,850 |
| Patents and licenses | 63,230 |
| In-process research and development | 169,000 |
| Deferred tax asset | 101,734 |
| Other non-current assets | 5,009 |
| Accounts payable and accrued expenses | (55,179) |
| Other long-term liabilities | (8,496) |
| Deferred tax liability | (268,688) |
| | \$ 1,801,183 |

As part of the purchase price allocation, IPR&D projects have been valued at \$169.0 million. These are projects that have not yet achieved technological feasibility as of the date of our acquisition of Biosite.

The preliminary aggregate purchase price, as adjusted, was allocated to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. Management has assigned an estimated useful life of 10.5 years for trademarks, a range of 1.5 years to 22.5 years for customer relationships, a range of 11.5 years to 19.5 years for core technology, and a range of 11.5 years to 14.5 years to patents and licenses and has recorded these assets in core technology and patents, net and other intangible assets, net in the accompanying consolidated balance sheet at September 30, 2007. The excess of the purchase price over the estimated fair value of

the assets acquired and liabilities assumed was allocated to goodwill. We expect that substantially all of the amount allocated to goodwill will not be deductible for tax purposes. The allocation of purchase price remains subject to potential adjustments, including adjustments for liabilities associated with certain exit activities and restructuring activities.

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

Table of Contents

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

(c) Acquisition of Quality Assurance Services, Inc.

On June 7, 2007, we acquired Quality Assurance Services, Inc. (QAS), a privately-owned provider of diagnostic home tests and services in the U.S. marketplace. The preliminary aggregate purchase price was \$25.4 million, which consisted of \$12.5 million in cash, 273,642 shares of our common stock with an aggregate fair value of \$12.8 million and \$0.1 million in direct acquisition costs

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

| | |
|---------------------------------------|-----------|
| Cash and cash equivalents | \$ 110 |
| Accounts receivable | 3,038 |
| Inventories | 470 |
| Other current assets | 24 |
| Property, plant and equipment | 1,198 |
| Goodwill | 19,866 |
| Trademarks | 2,500 |
| Customer relationships | 1,700 |
| Internally-developed software | 1,910 |
| Deferred tax asset | 29 |
| Accounts payable and accrued expenses | (3,561) |
| Long-term debt | (1,862) |
| | \$ 25,422 |

The preliminary aggregate purchase price, as adjusted, was allocated to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. Management has assigned an estimated useful life of 5 years, 11 years and 7 years to trademarks, customer relationships and internally-developed software, respectively, and has recorded these assets in other intangible assets, net in the accompanying consolidated balance sheet at September 30, 2007. The excess of the purchase price over the estimated fair value of the assets acquired and liabilities assumed was allocated to goodwill. We expect that the amount allocated to goodwill will not be deductible for tax purposes. The allocation of purchase price remains subject to potential adjustments.

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

(d) 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 aggregate purchase price was \$44.1 million, which consisted of \$30.6 million in cash, 313,888 shares of our common stock with an aggregate fair value of \$13.1 million and \$0.4 million in direct acquisition costs.

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

| | |
|-------------------------------|--------|
| Cash and cash equivalents | \$ 327 |
| Accounts receivable | 3,638 |
| Inventories | 4,267 |
| Other current assets | 780 |
| Property, plant and equipment | 141 |

| | |
|---------------------------------------|---------|
| Goodwill | 32,934 |
| Trademarks | 2,380 |
| Customer relationships | 19,010 |
| Accounts payable and accrued expenses | (4,279) |

Table of Contents

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

| | |
|---------------------------|-----------|
| Long-term debt | (4,925) |
| Other long-term liability | (1,220) |
| Deferred tax liability | (8,976) |
| | \$ 44,077 |

The above values for the assets acquired and liabilities assumed are based on final valuations. We estimate a useful life of 5 years and 12 years to trademarks and customer relationships, respectively, and have recorded these assets in other intangible assets, net in the accompanying consolidated balance sheet at September 30, 2007. The excess of the purchase price over the estimated fair value of the assets acquired and liabilities assumed was allocated to goodwill. We expect that the amount allocated to goodwill will not be deductible for tax purposes. The allocation of purchase price remains subject to potential adjustments.

The operating results of Instant are included in our professional diagnostic products reporting unit and business segment and the 25% minority interest is recorded in other long-term liabilities on our consolidated balance sheet at September 30, 2007.

(e) Acquisition of First Check Diagnostics LLC

On January 31, 2007, we acquired substantially all of the net 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 aggregate purchase price was approximately \$24.8 million, which consisted of \$24.5 million in cash and \$0.2 million in direct acquisition costs.

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

| | |
|---------------------------------------|-----------|
| Accounts receivable | \$ 1,539 |
| Inventories | 638 |
| Other current assets | 61 |
| Property, plant and equipment | 6 |
| Goodwill | 6,406 |
| Trademarks | 1,438 |
| Customer relationships | 15,145 |
| Non-compete agreements | 438 |
| Accounts payable and accrued expenses | (909) |
| | \$ 24,762 |

The above values for the assets acquired and liabilities assumed are based on final valuations. We estimate a useful life of 5 years, 10 years and 4 years for trademarks, customer relationships and the non-compete agreements, respectively, and have recorded these assets in other intangible assets, net in the accompanying consolidated balance sheet at September 30, 2007. The excess of the purchase price over the estimated fair value of the assets acquired and liabilities assumed was allocated to goodwill. We expect that the amount allocated to goodwill will be deductible for tax purposes. The allocation of purchase price remains subject to potential adjustments.

The operating results of First Check are included in our consumer diagnostic products reporting unit and business segment.

(f) Various Other Acquisitions

During the nine months period ending September 30, 2007, we acquired the following businesses for an aggregate purchase price of \$25.4 million, in which we paid in \$23.8 million in cash and issued 40,186 shares of our common stock with an aggregate fair value of \$1.6 million:

Spectral Diagnostics Private Limited and its affiliate Source Diagnostics (India) Private Limited
(Spectral/Source), located in New Delhi and Shimla, India, distributes professional diagnostic products in India

Table of Contents

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

52.45% share in Diamics, Inc. (Diamics), located in Novato, California, develops molecular-based cancer screening and diagnostic systems

Orange Medical (Orange), located in Tilburg, The Netherlands, a manufacturer and marketer of rapid diagnostic products to the Benelux marketplace

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

Med-Ox Chemicals Limited (Med-Ox), located in Ottawa, Canada, a distributor of professional diagnostic testing products in the Canadian marketplace

NSKK and Promesan are included in our consumer and professional diagnostic products reporting units and business segments and Spectral/Source, Orange, Gabmed and Med-Ox are included in our professional diagnostic products reporting unit and business segment. Diamics is fully consolidated and included in our professional diagnostic products reporting unit and business segment and the 25% minority interest is recorded in other long-term liabilities on our consolidated balance sheet at September 30, 2007. Goodwill has been recognized in the Spectral/Source, Diamics, Orange, Gabmed, Promesan and Med-Ox transactions and amounted to approximately \$17.0 million. Goodwill related to these acquisitions is not deductible for tax purposes.

(g) Restructuring Plans of Acquisitions

In connection with several of our acquisitions, we initiated integration plans to consolidate and restructure certain functions and operations, including the relocation and termination of certain personnel of these acquired entities and the closure of certain of the acquired entities leased facilities. These costs have been recognized as liabilities assumed in connection with the acquisition of these entities in accordance with EITF Issue No. 95-3 and are subject to potential adjustments as certain exit activities are confirmed or refined. The following table summarizes the liabilities established for exit activities related to these acquisitions (amounts in thousands):

| | Severance Related | Facility And Other | Total Exit Activities |
|-------------------------------|------------------------------|-----------------------------------|----------------------------------|
| Balance at December 31, 2005 | \$ 1,489 | \$ 939 | \$ 2,428 |
| Payments | (172) | (150) | (322) |
| Currency adjustments | 177 | | 177 |
| Balance at December 31, 2006 | 1,494 | 789 | 2,283 |
| Acquisitions | 16,695 | 20 | 16,715 |
| Payments | (3,029) | (118) | (3,147) |
| Currency adjustments | 48 | | 48 |
| Balance at September 30, 2007 | \$ 15,208 | \$ 691 | \$ 15,899 |

In conjunction with our acquisition of Biosite, we implemented an integration plan to improve efficiencies and eliminate redundant costs resulting from the acquisition. The restructuring plan impacted all cost centers within the

Biosite organization, as activities were combined with our existing business operations. We recorded \$12.4 million in exit costs, of which substantially all relate to change in control and severance costs to involuntarily terminate 137 employees in the Biosite organization.

Additionally, we formulated a restructuring plan in connection with our integration of the Cholestech business consistent with our acquisition strategy to realize efficiencies and cost savings and recorded \$4.3 million in exit costs related

Table of Contents

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

to change in control and severance costs to involuntarily terminate 29 employees, primarily executives.

(11) Restructuring Plans

(a) 2007 Restructuring Plans

In September 2007, we committed to a plan to improve efficiencies in operations resulting in the termination of certain employees at our headquarters in Waltham, Massachusetts, who were performing research and development related services for our research center in Stirling, Scotland. During the three months ended September 30, 2007, we recorded \$0.2 million to research and development expense associated with our professional diagnostic products business segment in connection with these terminations. The total number of employees to be involuntarily terminated under the plan is nine, of which six remain to be terminated as of September 30, 2007. As of September 30, 2007, all costs remain unpaid. We do not expect to incur any additional costs related to this plan.

In addition, we recorded restructuring charges associated with the formation of our joint venture with The Procter & Gamble Company (P&G). See Note 14(a)(i) for additional information on this plan.

(b) 2006 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. For the nine months ended September 30, 2007, we recorded \$0.4 million in net restructuring charges under these plans, which primarily relates to \$0.6 million in facility exit costs, offset by a \$0.2 million adjustment due to the finalization of fixed asset write-offs. Of the \$0.4 million net charge, the \$0.2 million adjustment was recorded to costs of sales, and was included in our consumer diagnostic products segment, and \$0.6 million was charged to general and administrative expense, and was included in our professional diagnostic products business segment.

We recorded \$1.2 million and \$11.0 million, respectively, in restructuring charges during the three and nine months ended September 30, 2006. The \$1.2 million charge for the three months ended September 30, 2006 related to severance charges. The \$11.0 million charge for the nine months ended September 30, 2006 included \$1.9 million related to severance charges, \$6.4 million related to impairment charges on fixed assets and \$2.7 million related to an impairment charge on an intangible asset. The \$11.0 million of charges for the nine months ended September 30, 2006 consisted of \$7.6 million charged to cost of sales, \$2.9 million charged to research and development and \$0.5 million charged to general and administrative expenses, of which \$1.6 million, \$6.5 million and \$2.9 million were included in our consumer diagnostic products, professional diagnostic products and corporate and other business segments, respectively.

Including the charges recorded through September 30, 2007, we have incurred total restructuring charges related to these plans of approximately \$12.4 million. The total number of employees to be involuntarily terminated under these plans is 131, all of whom have been terminated as of September 30, 2007. As of September 30, 2007, \$0.1 million of the severance related charges remains unpaid.

(c) 2005 Restructuring Plan

On May 9, 2005, we committed to a plan to cease operations at our facility in Galway, Ireland. During the nine months ended September 30, 2006, we recorded a net restructuring gain of \$3.2 million, of which \$0.4 million related to charges for severance, early retirement and outplacement services, \$0.1 million related to an impairment charge of fixed assets, \$0.6 million related to facility closing costs and \$4.3 million in foreign exchange gains as a result of recording a cumulative translation adjustment to other income relating primarily to this plan of termination. The charges for the nine months ended September 30, 2006 consisted of \$0.7 million, charged to cost of goods sold, \$0.4 million charged to general and administrative and \$4.3 million in gains recorded to other expense. Of the \$1.1

Table of Contents

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

million included in operating income for the nine months ended September 30, 2006, \$0.9 million was included in our consumer diagnostic products business segment and \$0.2 million was included in our professional diagnostic products business segments. Additionally, during the nine months ended September 30, 2006, we recorded a \$1.4 million gain on the sale of our CDIL facility in Ireland which has been recorded in loss on dispositions, net in our consolidated statements of operations and is included in our corporate and other business segment for this period.

(12) 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 September 30, 2007, we had received approximately £27.5 million (\$50.9 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 and nine months ended September 30, 2007, we recognized \$5.1 million and \$14.9 million of reimbursements, respectively, of which \$4.8 million and \$13.7 million, respectively, offset our research and development spending and \$0.3 million and \$1.2 million, respectively, reduced our general, administrative and marketing spending incurred by Stirling.

For the three and nine months ended September 30, 2006, we recognized \$4.7 million and \$13.6 million of reimbursements, respectively, of which \$4.3 million and \$12.2 million, respectively, offset our research and development spending and \$0.4 million and \$1.4 million, respectively, reduced our general, administrative and marketing spending incurred by Stirling.

(13) In-Process Research and Development

In connection with two of our acquisitions since 2006, we have acquired various IPR&D projects. Substantial additional research and development will be required prior to any of our acquired IPR&D programs and technology platforms reaching technological feasibility. In addition, once research is completed, each product candidate acquired will need to complete a series of clinical trials and receive FDA or other regulatory approvals prior to commercialization. Our current estimates of the time and investment required to develop these products and technologies may change depending on the different applications that we may choose to pursue. We cannot give assurances that these programs will ever reach technological feasibility or develop into products that can be marketed profitably. In addition, we cannot guarantee that we will be able to develop and commercialize products before our competitors develop and commercialize products for the same indications. If products based on our acquired IPR&D programs and technology platforms do not become commercially viable, our results of operations could be materially adversely affected.

The following table sets forth IPR&D projects for companies and certain assets we have acquired since 2006 (in thousands):

| Company/ Year Assets | Purchase | IPR&D | Programs Acquired | Discount Rate Used in Estimating Cash Flows(1) | Year of Expected Launch |
|-------------------------|----------|-------|-------------------|--|----------------------------|
| Acquired | Price | (1) | | Flows(1) | Launch |

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| | | | | | |
|--------------|--------------|------------|---------------------|-----|-----------|
| Biosite/2007 | \$ 1,800,000 | \$ 13,000 | Triage Sepsis Panel | 15% | 2008-2010 |
| | | 156,000 | Triage NGAL | 15% | 2008-2010 |
| | | \$ 169,000 | | | |

Table of Contents

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

| Company/ Year Assets | Purchase Price | IPR&D (1) | Programs Acquired | Discount Rate Used in Estimating Cash | Year of Expected Launch |
|-------------------------|-------------------|--------------|-------------------------------------|--|----------------------------|
| Acquired | | | | Flows(1) | |
| Clondiag/2006 | \$ 24,000 | \$ 1,800 | CHF (Congestive Heart Failure) | 37% | 2008-2009 |
| | | 2,500 | ACS (Acute Coronary Syndrome) | 37% | 2009-2010 |
| | | 660 | HIV (Human Immuno-deficiency Virus) | 37% | 2008-2009 |
| | | \$ 4,960 | | | |

(1) Management assumes responsibility for determining the valuation of the acquired IPR&D projects. The fair value assigned to IPR&D for each acquisition is estimated by discounting, to present value, the cash flows expected once the acquired projects have reached technological feasibility. The cash flows are probability adjusted to reflect the risks of advancement through the

product approval process. In estimating the future cash flows, we also considered the tangible and intangible assets required for successful exploitation of the technology resulting from the purchased IPR&D projects and adjusted future cash flows for a charge reflecting the contribution to value of these assets.

(14) Investments in Unconsolidated Entities

(a) Equity Method Investments

(i) Joint Venture with The Procter & Gamble Company

On May 17, 2007, we completed our 50/50 joint venture with P&G for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products, outside the cardiology, diabetes and oral care fields. At the closing, we transferred our related consumer diagnostic assets totaling \$45.9 million, other than our manufacturing and core intellectual property assets, to the joint venture, and P&G acquired its interest in the joint venture for a cash payment of approximately \$325.0 million.

In conjunction with the transfer of net assets to the joint venture, it was determined that the working capital components of the closing balance sheet for the consumer diagnostic business would be retained by us and, in lieu of these components, a note payable would be contributed by us to the joint venture in the amount of \$22.3 million. The note was payable in four installments, with \$2.0 million due at the date of note and three equal installments of \$6.7 million each on the 30th, 60th and 90th day, respectively, following the date of the note. As of September 30, 2007, the note had been repaid in full.

As part of the consummation of the joint venture, we entered into a shareholder agreement with P&G, setting forth each party's rights and obligations with respect to the joint venture. The joint venture is owned in equal parts by subsidiaries of our company and P&G (the Members). Each Member has the right to appoint three managers to the Board of Managers. In general, a majority vote by the Board of Managers is required to adopt or approve a business plan and budget; launch any new product; issue or incur significant debt; incur significant expenditures not provided for in the business plan and budget; file any material income or similar tax returns and reports; sublicense or license any of the joint venture's intellectual property rights; appoint or dismiss any senior officers of the joint venture; retain or otherwise appoint, or dismiss, the accountant and any primary legal advisor or financial advisor to the joint venture; commence or settle any significant litigation or arbitration; or market, or permit any distributor, commissionaire or sales agent to market the joint venture products under a third party's label brand except for private label brands in the ordinary course of business.

In certain circumstances, Members are required to make additional capital contributions on a pro rata basis in accordance with membership interests in amounts sufficient to meet the funding requirements of the joint venture

pursuant to the business plan and budget and fund such other working capital requirements, capital expenditures or other capital needs as may from time to time be determined by action of the Members, including the capital expenditures required in connection with the acquisition of any new business, and to fund any deficiency in the working capital or capital expenditure requirements.

We also entered into an option agreement with P&G, pursuant to which P&G has the right, for a period of 60 days commencing on the fourth anniversary date of the agreement, to require us to acquire all of P&G's interest in the joint venture at fair market value, and P&G has the right, upon certain material breaches by us of our obligations to the joint venture, to acquire all of our interest in the joint venture at fair market value. No gain on the proceeds that we received from P&G through the formation of the joint venture will be recognized in our financial statements until P&G's option to require us to purchase its interest in the joint venture expires. We have recorded the deferred gain of \$302.5 million on our accompanying consolidated balance sheet as of September 30, 2007.

Table of Contents

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

We also entered into a manufacturing agreement with P&G, whereby we will manufacture consumer diagnostic products and sell these products to the joint venture entity. In our capacity as the manufacturer of products for the joint venture, we recorded \$25.8 million and \$40.1 million, respectively, in manufacturing revenue for the three and nine months ended September 30, 2007 which are included in net product sales on our accompanying consolidated statement of operations.

Furthermore, we entered into certain transition and long-term services agreements with the joint venture, pursuant to which we will provide certain operational support services to the joint venture. Revenue related to these service agreements amounted to \$1.1 million and \$1.7 million, respectively, and are included in our net product sales on our consolidated statement of operations for the three and nine months ended September 30, 2007, which is included in net product sales on our accompanying consolidated statement of operations.

Upon completion of the arrangement to form the joint venture, we ceased to consolidate the operating results of our consumer diagnostic products business related to the joint venture and instead account for our 50% interest in the results of the joint venture under the equity method of accounting in accordance with APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*. For the three and nine months ended September 30, 2007, we recorded \$0.7 million and \$1.7 million, respectively, of earnings in equity earnings of unconsolidated entities, net of tax, on our accompanying consolidated statement of operations, which represented our share of the joint venture's net income for the period.

In connection with the joint venture, we committed to a plan to close one of our sales offices in Germany, as well as evaluate redundancies in all departments of the consumer diagnostic products business segment that are impacted by the formation of the joint venture. For the three and nine months ended September 30, 2007, we recorded \$0.4 million and \$1.0 million, respectively, in restructuring charges related to this plan, of which \$0.6 million relates to severance costs and \$0.4 million relates to facility and other exit costs. Of the \$1.0 million, \$0.2 million was charged to cost of sales, \$0.1 million was charged to research and development expense, \$0.4 million was charged to sales and marketing expense and \$0.3 million was charged to general and administrative expense. The total number of employees to be involuntarily terminated under this plan is 17 of which 9 have been terminated as of September 30, 2007. Of the total \$1.0 million in severance and exit costs, \$0.5 million remains unpaid as of September 30, 2007. We will continue to evaluate the impact of the joint venture formation on our on-going consumer-related operations and anticipate incurring additional charges related to this plan.

(ii) Vedalab S.A.

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. We account for our 40% investment in Vedalab under the equity method of accounting in accordance with APB Opinion No. 18. 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. For the three and nine months ended September 30, 2007, we recorded \$178,000 and \$0.2 million, respectively, in equity earnings of unconsolidated entities in our accompanying consolidated statement of operations, which represented our minority share of Vedalab's net income for the respective period.

(iii) TechLab, Inc.

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
18

Table of Contents

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

acquisition costs. We account for our 49% investment in TechLab under the equity method of accounting, in accordance with APB Opinion No. 18. In August 2007, we received \$0.6 million from TechLab 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. For the three and nine months ended September 30, 2007, we recorded \$0.2 million and \$0.7 million, respectively, in equity earnings of unconsolidated entities, net of tax, in our accompanying consolidated statement of operations, which represented our minority share of TechLab's net income for the respective period.

(b) 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, in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, 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 and record the change through unrealized gain in other income (expense), net on our accompanying consolidated statement of operations. As of September 30, 2007 and December 31, 2006, the warrant was valued at \$0.2 million and \$0.4 million, respectively.

(15) Marketable Securities

Marketable securities classified as current assets represent publicly-traded equity investments which are classified as available-for-sale and recorded at fair value using the specific identification method. Unrealized gains and losses (except for other than temporary impairments) are recorded in other comprehensive income (loss), which is reported as a component of stockholders' equity.

During the period December 2006 through February 2007, we acquired an aggregate 750,000 shares of Biosite common stock on the open market. Upon purchase, the shares were recorded at their market value, as measured by their closing price on the Nasdaq Capital Market. We classified the securities acquired through June 26, 2007 as non-current marketable securities in our accompanying consolidated balance sheet as we intended to hold these securities indefinitely. With the June 2007 consummation of our Biosite acquisition, we included these shares, at their original cost, as part of the purchase price.

(16) 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 Innoacon business), including ABON BioPharm (Hangzhou) Co., Ltd (ABON), the owner of a newly-constructed manufacturing facility in Hangzhou, China, Instant, Biosite and Cholestech, as if the acquisitions of these entities had occurred on January 1, 2006. Pro forma results also reflect the impacts of the formation of the joint venture for our consumer diagnostics business (Note 14(a)(i)) as if the joint venture had been formed 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.

Table of Contents

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

| | Three Months Ended | | Nine Months Ended | |
|---|---------------------------|-------------|--------------------------|--------------|
| | September 30, | | September 30, | |
| | 2007 | 2006 | 2007 | 2006 |
| | (in thousands, | | (in thousands, | |
| | except per share | | except per share | |
| | amounts) | | amounts) | |
| Pro forma net revenue | \$ 249,429 | \$ 219,521 | \$ 722,001 | \$ 656,410 |
| Pro forma net loss | \$ (7,626) | \$ (29,564) | \$ (25,576) | \$ (345,573) |
| Pro forma net loss per common share basic and diluted (1) | \$ (0.14) | \$ (0.69) | \$ (0.52) | \$ (8.43) |

(1) Net loss per common share amounts are computed as described in Note 6.

(17) Senior Credit Facilities

As of December 31, 2006, \$44.8 million of borrowings were outstanding under our then senior credit facility (the Prior Credit Agreement). 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 9), we paid the remaining principal balance outstanding and accrued interest under the Prior Credit Agreement. We terminated our Prior Credit Agreement in conjunction with our refinancing activities discussed below.

For the nine months ended September 30, 2007, interest expense, including amortization of deferred financing costs, under this senior credit facility was \$4.7 million. Included in interest expense for the nine months ended September 30, 2007, is the write-off of \$2.6 million, in unamortized deferred financing costs. For the three and nine months ended September 30, 2006, we recorded interest expense, including amortization of deferred financing costs, under this senior credit facility in the aggregate amount of \$2.7 million and \$6.9 million, respectively. We had no outstanding loans under the Prior Credit Agreement at the time it was terminated.

On June 26, 2007, in connection with our acquisition of Biosite, we entered into a secured First Lien Credit Agreement and a secured Second Lien Credit Agreement (collectively, the Credit Agreements) with certain lenders, General Electric Capital Corporation as administrative agent and collateral agent, and certain other agents and arrangers, and certain related guaranty and security agreements. The First Lien Credit Agreement provides for term loans in the aggregate amount of \$900.0 million and, subject to our continued compliance with the First Lien Credit Agreement, a \$150.0 million revolving line of credit. The Second Lien Credit Agreement provides for term loans in the aggregate amount of \$250.0 million. As of September 30, 2007, aggregate borrowings amounted to \$41.0 million under the revolving line of credit and \$1.1 billion under the term loans. Interest expense related to our new credit facility which included the term loans and revolving line of credit for the three and nine months ended September 30, 2007, including amortized deferred financing costs, was \$27.5 million and \$29.2 million, respectively. As of September 30, 2007, we were in compliance with all debt covenants related to the above debt.

In August 2007, we entered into interest rate swap contracts, with an effective date of September 28, 2007, that have a total notional value of \$350.0 million and have a maturity date of September 28, 2010. These interest rate swap

contracts will pay us variable interest at the three-month LIBOR rate, and we will pay the counterparties a fixed rate of 4.85%. These interest rate swap contracts were entered into to convert \$350.0 million of the \$1.3 billion variable rate term loan under the senior credit facility into fixed rate debt. Based on the terms of the interest rate swap contracts and the underlying debt, these interest rate swap contracts were determined to be effective, and thus qualify as a cash flow hedge under SFAS No. 133. As such, any changes in the fair value of these interest rate swaps are recorded in other comprehensive income on the accompanying consolidated balance sheet until earnings are affected by the variability of cash flows.

In addition, on June 26, 2007, we also fully repaid our 8.75% senior subordinated notes due 2012 (the Notes). The total amount repaid, including principal of \$150.0 million and a prepayment premium of \$9.3 million, was \$159.3 million. Accrued interest of \$4.8 million was also paid as part of the final settlement of these Notes and unamortized deferred financing costs of \$3.7 million were written off as a result of the repayment.

Additionally, we received proceeds from the May 14, 2007 sale of \$150.0 million principal amount of 3% convertible senior subordinated notes due 2016 (the Convertible Notes) in a private placement to qualified institutional buyers. At the initial conversion price of \$52.30, the Convertible Notes are convertible into an

Table of Contents

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

aggregate 2,868,120 shares of our common stock. The conversion price is subject to adjustment one year from the date of sale if the 30 day volume-weighted average trading price of our common stock as of such date is lower than \$40.23, subject to a floor of \$40.23, or from time to time in the event of stock splits, stock dividends, recapitalizations and other similar events. The conversion price is also subject to a make-whole payment in the form of an adjustment to the conversion price in the event of a fundamental change (as defined in the Indenture). Interest accrues at 3% per annum, compounded daily, on the outstanding principal amount and is payable in arrears on May 15th and Nov 15th, which will start on November 15, 2007. Interest expense for the three and nine months ended September 30, 2007, including amortized deferred costs, was \$1.2 million and \$1.8 million, respectively.

We evaluated the Convertible Notes agreement for potential embedded derivatives under SFAS No. 133 and related applicable accounting literature, including EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, and EITF Issue No. 05-4, *The Effect of a Liquidated Damages Clause on a Freestanding Financial Instrument Subject to Issue No. 00-19*. The conversion feature and the make-whole payment were determined to not meet the embedded derivative criteria as set forth by SFAS No. 133. Therefore, no fair value has been recorded for these items.

(18) Defined Benefit Pension Plan

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

| | Three Months Ended | | Nine Months Ended | |
|--------------------------------|---------------------------|-------------|--------------------------|-------------|
| | September 30, | | September 30, | |
| | 2007 | 2006 | 2007 | 2006 |
| Service cost | \$ | \$ | \$ | \$ |
| Interest cost | 155 | 144 | 458 | 420 |
| Expected return on plan assets | (129) | (120) | (381) | (349) |
| Realized losses | 89 | 83 | 262 | 240 |
| Net periodic benefit cost | \$ 115 | \$ 107 | \$ 339 | \$ 311 |

(19) 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 income of Professional Diagnostic Products are expenses related to our research and development activities in the area of cardiology for the three and nine months ended September 30, 2007, the latter of which amounted to \$8.6 million, net of the ITI funding (Note 12) of \$4.8 million, and \$18.4 million, net of the ITI funding of \$13.7 million, respectively. \$9.9 million, net of the ITI funding of \$4.3 million and \$22.1 million, net of \$12.2 million of the ITI funding, respectively, for the three and nine months ended September 30, 2006, respectively, and have been included in Corporate and Other. Operating loss of \$178.1 million and \$234.8 million, for the three and nine months ended September 30, 2007, respectively, in our Corporate and Other segment includes the write-off of \$169.0 million of IPR&D incurred in our acquisition of Biosite and for the nine months ended September 30, 2007, \$45.2 million of stock-based compensation related to employee stock options assumed in the acquisition of Biosite. Total assets related to our cardiology research

operations in Scotland and Germany, which are included in Professional Diagnostic Products in 2007 and included in Corporate and Other in 2006 in the tables below, amounted to \$37.7 million at September 30, 2007 and \$18.4 million at December 31, 2006.

We evaluate performance of our operating segments based on revenue and operating income (loss). Segment information for the three and nine months ended September 30, 2007 and 2006 is as follows (in thousands):

Table of Contents

| | Consumer Diagnostic Products | Vitamins and Nutritional Supplements | Professional Diagnostic Products | Corporate and Other | Total |
|-----------------------------------|---|---|---|------------------------------------|--------------|
| Three Months Ended | | | | | |
| September 30, 2007: | | | | | |
| Net revenue to external customers | \$ 33,263 | \$ 20,710 | \$ 183,663 | \$ | \$ 237,636 |
| Operating income (loss) | \$ 3,600 | \$ 607 | \$ 17,421 | \$ (178,103) | \$ (156,475) |
| Three Months Ended | | | | | |
| September 30, 2006: | | | | | |
| Net revenue to external customers | \$ 45,350 | \$ 18,462 | \$ 81,100 | \$ | \$ 144,912 |
| Operating income (loss) | \$ 6,373 | \$ (1,174) | \$ 11,941 | \$ (16,096) | \$ 1,044 |
| Nine Months Ended | | | | | |
| September 30, 2007: | | | | | |
| Net revenue to external customers | \$ 131,148 | \$ 53,643 | \$ 366,789 | \$ | \$ 551,580 |
| Operating income (loss) | \$ 16,098 | \$ (2,094) | \$ 38,119 | \$ (234,804) | \$ (182,681) |
| Nine Months Ended | | | | | |
| September 30, 2006: | | | | | |
| Net revenue to external customers | \$ 134,196 | \$ 59,559 | \$ 218,691 | \$ | \$ 412,446 |
| Operating income (loss) | \$ 23,234 | \$ (2,223) | \$ 22,494 | \$ (45,654) | \$ (2,149) |
| Assets: | | | | | |
| As of September 30, 2007 | \$ 309,841 | \$ 49,216 | \$ 3,048,151 | \$ 84,333 | \$ 3,491,541 |
| As of December 31, 2006 | \$ 314,815 | \$ 49,896 | \$ 625,560 | \$ 95,500 | \$ 1,085,771 |

(20) Related Party Transaction

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). Under the terms of the agreement, the loan amount would simultaneously convert into shares of the related party's common stock per the prescribed conversion formula defined in the loan agreement, in the event the related party consummated a specific target acquisition on or before September 30, 2007. On May 15, 2007, the related party consummated a specific target acquisition and the loan converted into 5,208,333 shares of the related party's common stock which is included in investments in unconsolidated entities on our accompanying consolidated balance sheet at September 30, 2007.

(21) 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 September 30, 2007, we had contingent consideration obligations related to our acquisitions of Spectral/Source, 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 Spectral/Source, we will pay an earn-out equal to two times the consolidated revenue of Spectral/Source less \$4.0 million, if the consolidated profits before tax of Spectral/Source is at least \$0.9 million on the one year anniversary (milestone period) following the acquisition date. If consolidated profits before tax of Spectral/Source for the milestone period are less than \$0.9 million, then the amount of the payment will be equal to seven times Spectral/Source's consolidated profits before tax less \$4.0 million. The contingent consideration is payable 60% in cash and 40% in stock.

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

Table of Contents

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

seller 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. 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 not an employee of the company at the time of exercise, the full consideration will be payable in cash. The option will 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. During the three months ended September 30, 2007, we paid and recorded \$3.7 million related to the successful development of one of the qualifying products.

With respect to Clondrag, 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 Clondrag's platform technology during the three years following the acquisition date.

(22) 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.

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.

In June 2007, the EITF reached a consensus on EITF Issue No. 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. This consensus is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier adoption is not permitted. The effect of applying the consensus will be prospective for new contracts entered into on or after that date. We do not believe that adoption of the consensus in the first quarter of 2008 will have a material impact on our consolidated financial statements.

Table of Contents

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

Recently Adopted 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 7 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 EITF Issue No. 06-03 is effective for interim and annual reporting periods beginning after December 15, 2006. As required by EITF Issue 06-03, we adopted this new accounting standard for the interim period beginning January 1, 2007. The adoption of EITF Issue 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 a 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, and No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* and FIN 45, *Guarantors 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 is 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.

(23) Guarantor Financial Information

On June 26, 2007, we fully repaid our \$150.0 million in senior subordinated notes which we previously issued 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 were guaranteed by all of our domestic subsidiaries. As a result of our payment in full, guarantor

financial information is no longer required.

Table of Contents

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Financial Overview

We are a global leader in rapid point-of-care diagnostic products. Through our professional diagnostic products segment, we develop, manufacture and market an extensive array of innovative rapid diagnostic test products and other in vitro diagnostic tests to medical professionals and laboratories for detection of infectious diseases, cardiac conditions, drugs of abuse and pregnancy. Our professional products are sold in approximately 90 countries through a direct sales force and an extensive network of independent global distributors. Our consumer diagnostic products segment consists primarily of manufacturing operations related to our role as the exclusive manufacturer of products for SPD Swiss Precision Diagnostics (Swiss Precision), our 50/50 joint venture with The Procter & Gamble Company (P&G). Swiss Precision holds a leadership position in the worldwide over-the-counter pregnancy and fertility/ovulation test market. We also manufacture and market a variety of vitamins and nutritional supplements under our other brands and those of private label retailers primarily in the U.S. consumer market.

We have grown our businesses by leveraging our strong intellectual property portfolio and making selected strategic acquisitions. We plan to continue to pursue selective acquisitions, particularly acquisitions that would increase the market penetration and breadth of our product offerings and expand our distribution capabilities. We may incur additional indebtedness in connection with those acquisitions. We are also focused on improving our margins through consolidation of certain of our manufacturing operations at lower costs facilities. Our acquisition of the Innovacon business represents a key component of this strategy. During 2007, we are seeing improved margins on some of our existing products as we move production of certain products from higher costs facilities to our ABON facility in Hangzhou, China.

Our 50/50 joint venture with P&G, consummated during the second quarter of 2007, continues to expand the reach of our over-the-counter diagnostic products, while enabling enhanced focus on our rapidly growing professional diagnostic products segment and, in particular, on our cardiology development programs. Our acquisition of Biosite, Inc. (Biosite), during the second quarter of 2007 has also expanded our product offerings and research capabilities, particularly in the area of cardiology diagnostics.

During the third quarter of 2007, we completed several acquisitions, including that of Cholestech Corporation (Cholestech), which together provide us the unique ability to assess cardiac risk, diagnose cardiac conditions and potentially monitor the condition and response to therapy of cardiac patients. The Cholestech acquisition was consummated pursuant to a merger agreement on September 12, 2007.

On October 18, 2007, we announced the implementation of several plans to restructure and integrate our U.S. sales, marketing, order management and fulfillment operations. The objectives of the plans are to eliminate redundant costs resulting from acquisitions, including our recent acquisitions of Biosite and Cholestech, and to improve customer responsiveness and efficiencies in operations. We additionally announced our plan to transition to a shared service center model in North America. We anticipate significant cost savings to our businesses as a result of these plans.

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 portfolios, which underlie our emphasis on new product development, against potential infringers.

For the three and nine months ended September 30, 2007, we recorded net revenue of \$237.6 million and \$551.6 million, respectively, compared to \$144.9 million and \$412.4 million, respectively for the three and nine months ended September 30, 2006. The revenue increase was primarily due to increased sales in our professional diagnostic products segment, contributed by businesses acquired which contributed \$94.3 million of the increased product revenue. Adjusted for the favorable impact of currency translation, net revenue of \$235.7 million for the three months ended September 30, 2007 was approximately 63% higher than for the three months ended September 30, 2006 and net revenue of \$543.4 million for the nine months ended September 30, 2007 was approximately 32% higher than for the comparable nine months ended September 30, 2006. Our reported consumer diagnostic products segment net revenue for the three months ended September 30, 2007 was adversely impacted as a result of the May 17, 2007 formation of our joint venture with P&G, as we no longer consolidate the results of this portion of our business

beginning on May 18, 2007, but account for our 50% interest under the equity method of accounting. Accordingly, after May 17, 2007, the results from our ownership interest in the joint venture are reported on our accompanying consolidated statements of operations in

Table of Contents

equity earnings of unconsolidated entities for the three and nine months ended September 30, 2007. During the three and nine months ended September 30, 2007, we reported \$0.7 million and \$1.7 million, respectively, in equity earnings, net of tax, related to this joint venture. Our vitamins and nutritional supplements business segment experienced a 12% increase in net product revenue for the three months ending September 30, 2007, compared to the comparable period in 2006, and a 10% decrease in net product revenue for the first nine months of 2007, compared to the first nine months of 2006.

For the three and nine months ended September 30, 2007, we incurred a net loss of \$180.6 million and \$229.0 million, respectively, compared to a net loss of \$9.7 million and \$22.9 million, respectively, for the three and nine months ended September 30, 2006. The net loss in both of the 2007 periods are primarily attributed to a \$169.0 million write-off of in-process research and development projects at Biosite based on appraised values. The nine month loss in 2007 also included a \$45.2 million stock-based compensation charge associated with the acceleration and conversion of employee stock options in conjunction with our acquisition of Biosite and a write-off of \$15.4 million of deferred financing costs and prepayment penalty related to the repayment of our outstanding debt in conjunction with our financial arrangements related to our Biosite acquisition.

Recent Developments

On August 6, 2007, we entered into a merger agreement to acquire HemoSense, Inc. (HemoSense), a point-of-care diagnostic healthcare company that manufactures and sells easy-to-use, handheld blood coagulation systems for monitoring patients taking warfarin, in a stock for stock merger at a fixed exchange ratio of 0.274192 shares of our common stock for each share of common stock of HemoSense. Based on this exchange ratio, we issued approximately 3,691,387 shares of our common stock to the HemoSense shareholders, and reserved approximately 655,242 shares of our common stock for future issuance upon the exercise of assumed options and warrants. The merger was completed on November 6, 2007. The transaction was structured as a tax-free reorganization.

On October 24, 2007, we entered into an agreement to acquire Alere Medical, Inc. (Alere), a leading provider of health and care management services helping patients with chronic illnesses manage their conditions through a unique combination of at-home monitoring, patient education and nurse-patient relationships. The purchase price is \$302.0 million, comprising approximately \$125.0 million in cash and \$177.0 million in our common stock. The transaction is expected to close prior to the end of the calendar year, subject to satisfaction of regulatory and other customary closing conditions.

Results of Operations

Net Product Sales, Total and by Business Segment. Total net product sales increased by \$87.7 million, or 62%, to \$228.6 million for the three months ended September 30, 2007 from \$140.9 million for the three months ended September 30, 2006. Excluding the favorable impact of currency translation, net product sales for the three months ended September 30, 2007 increased by \$85.7 million, compared to the three months ended September 30, 2006. Total net product sales increased by \$134.3 million, or 34%, to \$534.5 million for the nine months ended September 30, 2007 from \$400.2 million for the nine months ended September 30, 2006. Excluding the favorable impact of currency translation, net product sales for the nine months ended September 30, 2007 increased by \$126.1 million, compared to the nine months ended September 30, 2006. Net product sales by business segment for the three and nine months ended September 30, 2007 and 2006 are as follows (in thousands):

| | Three Months Ended | | | Nine Months Ended | | |
|--------------------------------------|-----------------------|-----------------------|-------------|-----------------------|-----------------------|-------------|
| | September 30, 2007 | September 30, 2006 | % Change | September 30, 2007 | September 30, 2006 | % Change |
| Consumer diagnostic products | \$ 30,330 | \$ 43,885 | (31)% | \$ 126,397 | \$ 129,427 | (2)% |
| Vitamins and nutritional supplements | 20,710 | 18,462 | 12% | 53,643 | 59,559 | (10)% |
| Professional diagnostic products | 177,528 | 78,549 | 126% | 354,481 | 211,260 | 68% |

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| | | | | | | |
|-------------------------|------------|------------|-----|------------|------------|-----|
| Total net product sales | \$ 228,568 | \$ 140,896 | 62% | \$ 534,521 | \$ 400,246 | 34% |
|-------------------------|------------|------------|-----|------------|------------|-----|

Table of Contents*Consumer Diagnostic Products*

Net product sales of our consumer diagnostic products decreased by \$13.6 million, or 31%, comparing the three months ended September 30, 2007 to the three months ended September 30, 2006. Net product sales of our consumer diagnostic products decreased by \$3.0 million, or 2%, comparing the nine months ended September 30, 2007 to the nine months ended September 30, 2006. Excluding the favorable impact from currency translation, net product sales of our consumer diagnostic products decreased by \$14.4 million, or 33%, and decreased \$7.8 million, or 6%, respectively, comparing the three and nine months ended September 30, 2007 with the three and nine months ended September 30, 2006. The May 17, 2007 formation of our 50/50 joint venture (Swiss Precision) with P&G impacted our reported results for our consumer diagnostic products, as we account for the results of the joint venture under the equity method of accounting and, as of May 17, 2007, no longer consolidate the results for this portion of our business in our consumer diagnostic products segment. Net product sales of our consumer diagnostic products for the three and nine months ended September 30, 2007 does however include \$25.8 million and \$40.1 million, respectively, of manufacturing revenue associated with our manufacturing agreement with Swiss Precision, whereby we manufacture and sell consumer diagnostic products to the joint venture. Our recent acquisition of First Check in January 2007 contributed \$3.5 million and \$9.2 million, respectively, in net product sales during the three and nine months ended September 30, 2007 associated with sales of over-the-counter drugs of abuse products.

Vitamins and Nutritional Supplements

Our vitamins and nutritional supplements net product sales increased by \$2.2 million, or 12%, comparing the three months ended September 30, 2007 to the three months ended September 30, 2006 and decreased by \$5.9 million, or 10%, comparing the nine months ended September 30, 2007 to the nine months ended September 30, 2006. The increase in the comparative three-month period is largely attributed to a partial recovery in our private label business which was impacted as a result of several large customers reducing their inventory levels in prior quarters. The decrease in the comparative nine-month period is reflective of continuing competitive pressures, particularly in our private label business.

Professional Diagnostic Products

Net product sales of our professional diagnostic products increased by \$99.0 million, or 126%, comparing the three months ended September 30, 2007 to the three months ended September 30, 2006. Excluding the favorable impact from currency translation, net product sales of our professional diagnostic products increased by \$97.9 million, or 125%, comparing the three months ended September 30, 2007 to the three months ended September 30, 2006. Of the currency adjusted increase, net product sales increased as a result of our acquisitions of: (i) Biosite in June 2007, which contributed \$77.2 million, (ii) Cholestech in September 2007, which contributed \$6.6 million, (iii) QAS in June 2007, which contributed \$5.3 million, and (iv) various less significant acquisitions, which contributed an aggregate of \$5.1 million. Organic growth of approximately 5% also contributed to the increase, as a result of growth in our clinical product sales and as we continued to gain market share particularly with our highly differentiated, higher margin brands and our private label offerings.

Net product sales of our professional diagnostic products increased by \$143.2 million, or 68%, comparing the nine months ended September 30, 2007 to the nine months ended September 30, 2006. Excluding the favorable impact from currency translation, net product sales of our professional diagnostic products increased by \$139.8 million, or 66%, comparing the nine months ended September 30, 2007 to the nine months ended September 30, 2006. Of the currency adjusted increase, net product sales increased as a result of our acquisitions of: (i) Biosite in June 2007, which contributed \$85.2 million, (ii) QAS in June 2007, which contributed \$6.7 million, (iii) Cholestech in September 2007, which contributed \$6.6 million, (iv) Instant in March 2007, which contributed \$6.3 million, (v) the Innovacon business in March 2006, which contributed \$10.3 million and (vi) various less significant acquisitions, which contributed an aggregate of \$12.5 million. Organic growth of approximately 6% also contributed to the increase during the nine-month period, as a result of growth in our clinical product sales and as we continued to gain market share particularly with our highly differentiated, higher margin brands and our private label offerings.

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 \$5.1 million, or 126%, to \$9.1 million for the three months ended September 30, 2007 from \$4.0 million for the three months

Table of Contents

ended September 30, 2006 and increased by approximately \$4.9 million, or 40%, to \$17.1 million for the nine months ended September 30, 2007 from \$12.2 million for the nine months ended September 30, 2006. The increase for the comparative three and nine-month periods reflects \$2.8 million of incremental royalty revenue contributed by Biosite, which was acquired in June 2007. Additionally, incremental royalty revenue was derived from new royalty agreements entered into during 2007, along with increases associated with certain existing royalty agreements, partially offset by decreases in other royalty arrangements.

Gross Profit and Margin. Gross profit increased by \$49.2 million, or 80%, to \$110.3 million for the three months ended September 30, 2007 from \$61.1 million for the three months ended September 30, 2006. Gross profit during the three months ended September 30, 2007 benefited primarily from higher than average margins earned on revenue from our recently acquired businesses, as discussed above, and higher margins achieved as a result of our lower manufacturing costs associated with our China facility. Included in cost of sales for the three months ended September 30, 2007 was a \$6.3 million charge related to the write-up to fair market value of inventory acquired in connection with our acquisitions of Biosite and Cholestech. Included in cost of sales for the three months ended September 30, 2006 is a \$1.2 million restructuring charge related to the closure of our ABI operation in San Diego, California, along with the write-off of fixed assets at other facilities impacted by restructuring plans.

Gross profit increased by \$93.1 million, or 57%, to \$255.0 million for the nine months ended September 30, 2007 from \$161.9 million for the nine months ended September 30, 2006. Gross profit during the nine months ended September 30, 2007 benefited primarily from higher than average margins earned on revenue from our recently acquired businesses, as discussed above, and higher margins achieved as a result of our lower manufacturing costs associated with our China facility. Included in cost of sales for the nine months ended September 30, 2007 was a \$7.5 million charge related to the Biosite and Cholestech acquisitions mentioned above. Cost of sales for the nine months ended September 30, 2006 included \$8.3 million in restructuring charges related to the closure of our Galway, Ireland manufacturing facility and our Applied Biotech, Inc. (ABI) operation in San Diego, California, along with the write-off of fixed assets at other facilities impacted by restructuring plans.

Cost of sales included intangible amortization expense of \$7.5 million and \$3.2 million for the three months ended September 30, 2007 and 2006, respectively, and \$13.8 million and \$8.5 million for the nine months ended September 30, 2007 and 2006, respectively.

Overall gross margin was 46% and 46% for the three and nine months ended September 30, 2007, respectively, compared to 42% and 39% for the three and nine months ended September 30, 2006, respectively.

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 \$44.9 million, or 77%, to \$103.4 million for the three months ended September 30, 2007 from \$58.5 million for the three months ended September 30, 2006. Gross profit from total net product sales increased by \$91.7 million, or 60%, to \$245.4 million for the nine months ended September 30, 2007 from \$153.7 million for the nine months ended September 30, 2006. Gross profit from net product sales by business segment for the three and nine months ended September 30, 2007 and 2006 are as follows (in thousands):

| | Three Months Ended | | | Nine Months Ended | | |
|---|-----------------------|-----------|-------------|-----------------------|------------|-------------|
| | September 30, 2007 | 2006 | % Change | September 30, 2007 | 2006 | % Change |
| Consumer diagnostic products | \$ 4,618 | \$ 22,410 | (79)% | \$ 51,640 | \$ 63,586 | (19)% |
| Vitamins and nutritional supplements | 2,605 | 828 | 215% | 3,900 | 3,842 | 2% |
| Professional diagnostic products | 96,141 | 35,229 | 173% | 189,881 | 86,316 | 120% |
| Total gross profit from net product sales | \$ 103,364 | \$ 58,467 | 77% | \$ 245,421 | \$ 153,744 | 60% |

Consumer Diagnostic Products

Gross profit from our consumer diagnostic product sales decreased by \$17.8 million, or 79%, to \$4.6 million for the three months ended September 30, 2007, compared to \$22.4 million for the three months ended September 30, 2006. The decrease during the three months ended September 30, 2007 is primarily a result of the formation of the joint venture for our consumer diagnostics business on May 17, 2007, partially offset by the gross profit earned on

28

Table of Contents

revenue from acquired businesses, primarily our First Check acquisition, as discussed above, and the 5% markup on products sold under our manufacturing agreement with Swiss Precision.

Gross profit from our consumer diagnostic product sales decreased by \$11.9 million, or 19%, to \$51.6 million for the nine months ended September 30, 2007, compared to \$63.6 million for the nine months ended September 30, 2006. The decrease during the nine months ended September 30, 2007 is primarily a result of the formation of the joint venture for our consumer diagnostics business on May 17, 2007, partially offset by the gross profit earned on revenue from acquired businesses, primarily our First Check acquisition, as discussed above, and the 5% markup on products sold under our manufacturing agreement with Swiss Precision. Included in cost of sales for the nine months ended September 30, 2006 was a \$2.2 million restructuring charge related to the closure of our Galway, Ireland manufacturing facility, the write-off of fixed assets impacted by our 2006 restructuring plans.

As a percentage of our consumer diagnostic net product sales, gross margin for the three and nine months ended September 30, 2007 was 15% and 41%, respectively, compared to 51% and 49% for the three and nine months ended September 30, 2006, respectively.

Vitamins and Nutritional Supplements

Gross profit in our vitamins and nutritional supplements business increased by \$1.8 million, to \$2.6 million for the three months ended September 30, 2007, compared to \$0.8 million for the three months ended September 30, 2006. Gross profit in our vitamins and nutritional supplements business increased by \$0.1 million, or 2%, to \$3.9 million for the nine months ended September 30, 2007, compared to \$3.8 million for the nine months ended September 30, 2006. Gross profit was relatively flat year over year for the nine-month periods.

As a percentage of our vitamins and nutritional supplements net product revenue, gross margin for the three and nine months ended September 30, 2007 was 13% and 7%, respectively, compared to 4% and 6% for the three and nine months ended September 30, 2006, respectively.

Professional Diagnostic Products

Gross profit from our professional diagnostic product sales increased by \$60.9 million, or 173%, to \$96.1 million during the three months ended September 30, 2007, compared to \$35.2 million for the three months ended September 30, 2006. The increase in gross profit was largely attributable to the increase in product sales resulting primarily from our acquisitions of Cholestech, Biosite and Instant, as discussed above, which contributed higher than average gross profits.

Gross profit from our professional diagnostic product sales increased by \$103.6 million, or 120%, to \$189.9 million during the nine months ended September 30, 2007, compared to \$86.3 million for the nine months ended September 30, 2006. The increase in gross profit was largely attributable to the increase in product sales resulting primarily from our acquisition of Cholestech, Biosite, QAS, Instant, and the Innovacon business which contributed higher than average gross profits.

As a percentage of our professional diagnostic net product sales, gross margin for the three and nine months ended September 30, 2007 was 54% and 54%, respectively, compared to 45% and 41% for the three and nine months ended September 30, 2006, respectively.

Research and Development Expense. Research and development expense increased by \$9.5 million, or 86%, to \$20.5 million for the three months ended September 30, 2007, compared to \$11.1 million for the three months ended September 30, 2006. The increase in research and development expense during the three months ended September 30, 2007 was primarily related to our cardiology programs and incremental spending associated with our acquired businesses, partially offset by the transition of our consumer-related research and development efforts into our joint venture during the second quarter of 2007. Research and development expense increased by \$9.9 million, or 28%, to \$44.6 million for the nine months ended September 30, 2007, compared to \$34.8 million for the nine months ended September 30, 2006. The overall increased spending in the comparative nine-month period was primarily related to our cardiology programs and incremental spending related to our acquired businesses, partially offset by the transition of our consumer-related research and development efforts into our joint venture during the second quarter

Table of Contents

of 2007. Restructuring charges associated with our formation of the joint venture and our 2007 restructuring plan to integrate our newly acquired businesses totaling \$0.3 million were included in research and development expense for the three and nine months ended September 30, 2007.

Research and development expense of \$20.5 million during the three months ended September 30, 2007 was partially offset by \$4.8 million of funding from ITI earned during the three month period, which represented an increase in funding of \$0.5 million over the comparable three month period in 2006, and \$0.2 million of unfavorable impact resulting from foreign currency translation. Research and development expense of \$44.6 million for the nine months ended September 30, 2007 was partially offset by \$13.7 million of funding from ITI earned during the nine month period, which represented an increase in funding of \$1.5 million over the comparable nine month period in 2006, and \$0.9 million of unfavorable impact resulting from foreign currency translation.

Research and development expense included intangible amortization expense of \$0.6 million and \$1.0 million for the three months ended September 30, 2007 and 2006, respectively, and \$2.2 million and \$2.3 million for the nine months ended September 30, 2007 and 2006, respectively.

As a percentage of net product sales, research and development expense was 9% and 8% for the three and nine months ended September 30, 2007, respectively, compared to 8% and 9% for the three and nine months ended September 30, 2006, respectively.

Purchase of In-Process Research and Development (IPR&D). In connection with two of our acquisitions since 2006, we have acquired various IPR&D projects. Substantial additional research and development will be required prior to any of our acquired IPR&D programs and technology platforms reaching technological feasibility. In addition, once research is completed, each product candidate acquired will need to complete a series of clinical trials and receive FDA or other regulatory approvals prior to commercialization. Our current estimates of the time and investment required to develop these products and technologies may change depending on the different applications that we may choose to pursue. We cannot give assurances that these programs will ever reach technological feasibility or develop into products that can be marketed profitably. In addition, we cannot guarantee that we will be able to develop and commercialize products before our competitors develop and commercialize products for the same indications. If products based on our acquired IPR&D programs and technology platforms do not become commercially viable, our results of operations could be materially adversely affected. The following table sets forth IPR&D projects for companies and certain assets we have acquired since 2006 (amounts in thousands):

| Company/ Year | Assets | Purchase Price | IPR&D (1) | Programs Acquired | Discount Rate Used in Estimating | Year of Expected Launch | Estimated Cost to Complete |
|------------------|--------------|-------------------|--------------|-------------------------------------|---|-------------------------------|----------------------------------|
| | | | | | Cash Flows(1) | | |
| Biosite/2007 | \$ 1,800,000 | \$ 13,000 | 156,000 | Triage Sepsis Panel | 15% | 2008-2010 | |
| | | | | Triage NGAL | 15% | 2008-2010 | |
| | | \$ 169,000 | | | | | \$ 6,000 |
| Clondiag/2006 | \$ 24,000 | \$ 1,800 | | CHF (Congestive Heart Failure) | 37% | 2008-2009 | |
| | | 2,500 | | ACS (Acute Coronary Syndrome) | 37% | 2009-2010 | |
| | | 660 | | HIV (Human Immuno-deficiency Virus) | 37% | 2008-2009 | |

\$ 4,960

\$ 9,500

(1) Management assumes responsibility for determining the valuation of the acquired IPR&D projects. The fair value assigned to IPR&D for each acquisition is estimated by discounting, to present value, the cash flows expected once the acquired projects have reached technological feasibility. The cash flows are probability adjusted to reflect the risks of advancement through the product approval process. In estimating the future cash flows, we also considered the tangible and intangible assets required for successful exploitation of the technology resulting from the purchased IPR&D projects and adjusted future cash flows for a charge reflecting the contribution

to value of these
assets.

Sales and Marketing Expense. Sales and marketing expense increased by \$22.6 million, or 87%, to \$48.5 million for the three months ended September 30, 2007, compared to \$26.0 million for the three months ended September 30, 2006. Sales and marketing expense increased by \$35.3 million, or 51%, to \$104.8 million for the nine months ended September 30, 2007, compared to \$69.5 million for the nine months ended September 30, 2006. The

30

Table of Contents

increase in sales and marketing expense for the three months ended September 30, 2007 was primarily the result of approximately \$22.3 million of additional spending related to newly acquired businesses, primarily Biosite, QAS, First Check, Instant, Cholestech and the various less significant acquisitions, a \$0.1 million charge related to our restructuring plan associated with the formation of our joint venture and a \$0.3 million of unfavorable impact resulting from foreign currency translation. The increase in sales and marketing expense for the nine months ended September 30, 2007 was primarily the result of approximately \$29.9 million of additional spending related to our acquisitions, primarily Biosite, First Check, QAS, Instant, the Innovacon business, Cholestech and the various less significant acquisitions, higher advertising expenditures associated with the introduction of our next generation branded digital pregnancy test, a \$0.4 million charge related to our restructuring plan associated with the formation of our joint venture and \$1.3 million of unfavorable impact resulting from foreign currency translation.

Intangible asset amortization related to customer relationships is included in sales and marketing expense. For the three and nine months ended September 30, 2007, sales and marketing expense included intangible amortization expense of \$11.6 million and \$19.9 million, respectively. For the three and nine months ended September 30, 2006, sales and marketing expense included intangible amortization expense of \$2.1 million and \$5.3 million, respectively.

As a percentage of net product sales, sales and marketing expense was 21% and 20% for the three and nine months ended September 30, 2007, respectively, compared to 18% and 17% for the three and nine months ended September 30, 2006.

General and Administrative Expense. General and administrative expense increased \$10.6 million, or 59%, to \$28.7 million for the three months ended September 30, 2007, compared to \$18.1 million for the three months ended September 30, 2006. General and administrative expense increased \$67.6 million, or 131%, to \$119.2 million for the nine months ended September 30, 2007, compared to \$51.6 million for the nine months ended September 30, 2006. The increase in general and administrative expense for the three months ended September 30, 2007 included approximately \$8.4 million of additional spending related to our acquisitions of Biosite, Instant, QAS, Cholestech, First Check and the various less significant acquisitions, a \$0.1 million charge related to our restructuring plan associated with the formation of our joint venture, an approximate \$1.1 million increase in legal spending and \$0.3 million of unfavorable impact resulting from foreign currency translation. The increase in general and administrative expense for the nine months ended September 30, 2007 included a \$45.2 million stock option charge associated with stock option acceleration and conversion in connection with our recent acquisition of Biosite, approximately \$12.9 million of additional spending related to our acquisitions, including Biosite, Instant, the Innovacon business, First Check, QAS, Cholestech and the various less significant acquisitions, a \$0.2 million charge related to the formation of our joint venture mentioned above, a \$0.6 million restructuring charge related to the closure of our San Diego, California manufacturing facility and \$1.4 million of unfavorable impact resulting from foreign currency translation, partially offset by a decrease in legal spending of \$2.8 million.

General and administrative expense included intangible amortization expense of \$0.1 million and \$0.1 million for the three months ended September 30, 2007 and 2006, and \$0.2 million and \$0.3 million for the nine months ended September 30, 2007 and 2006, respectively. The amortization expense recorded to general and administrative expense relates primarily to non-compete agreements.

As a percentage of net revenue, general and administrative expense for the three and nine months ended September 30, 2007 was 12% and 22%, respectively, compared to 12% and 13% for the three and nine months ended September 30, 2006, respectively.

Loss on Dispositions, Net. During the nine months ended September 30, 2006, we recorded a net loss of \$3.2 million. Included in this charge is a loss of \$4.6 million associated with management's decision to dispose of our SMB research operation. The \$4.6 million charge included a loss of \$2.0 million on impaired assets, most of which represents goodwill associated with SMB, and a \$2.6 million estimated loss on the sale of SMB. We disposed of this operation in the fourth quarter of 2006. The \$4.6 million loss is offset by a \$1.4 million gain on the sale of an idle manufacturing facility in Galway, Ireland, as a result of our 2005 restructuring plan.

Interest Expense. Interest expense included interest charges, the write-off and amortization of deferred financing costs, prepayment premiums, and the amortization of non-cash discounts associated with our debt

Table of Contents

issuances. Interest expense increased by \$20.8 million, or 254%, to \$29.0 million for the three months ended September 30, 2007, compared to \$8.2 million for the three months ended September 30, 2006. Interest expense increased by \$35.4 million, or 170%, to \$56.2 million for the nine months ended September 30, 2007, compared to \$20.8 million for the nine months ended September 30, 2006. Interest expense for the nine months ended September 30, 2007 included the write-off of \$15.6 million of deferred financing costs and prepayment premium related to the repayment of outstanding debt, in conjunction with our financing arrangements related to our Biosite acquisition. Interest expense increased for both periods as a result of higher debt balances than in prior periods.

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 | | | Nine Months Ended | | |
|---|-----------------------|----------|--------------|-----------------------|----------|--------------|
| | September 30, 2007 | 2006 | \$ Change | September 30, 2007 | 2006 | \$ Change |
| Interest income | \$ 1,412 | \$ 439 | \$ 973 | \$ 7,678 | \$ 1,058 | \$ 6,620 |
| Foreign exchange gains (losses), net | 1,290 | (107) | 1,397 | 2,615 | 3,236 | (621) |
| Other | (559) | (1,245) | 686 | (1,471) | (334) | (1,137) |
| Total other income (expense), net | \$ 2,143 | \$ (913) | \$ 3,056 | \$ 8,822 | \$ 3,960 | \$ 4,862 |

Interest income of \$1.4 million and \$7.7 million for the three and nine months ended September 30, 2007, respectively, increased \$1.0 million and \$6.6 million, respectively, compared to the three and nine months ended September 30, 2006, respectively. This increase was primarily the result of interest earned on higher cash balances.

Included in foreign exchange gains (losses), net for the nine months ended September 30, 2007 was a \$1.9 million foreign exchange realized upon the settlement of intercompany notes. Included in foreign exchange gains (losses), net for the nine months ended September 30, 2006 was a \$4.3 million unrealized foreign exchange gain associated with the closure of our Galway, Ireland manufacturing facility.

Other loss of \$0.5 million for the three months ended September 30, 2007, primarily reflects minority interest expense related to our less than wholly-owned subsidiaries and other investments. Other loss of \$1.5 million for the nine months ended September 30, 2007, primarily reflects minority interest expense related to our less than wholly-owned subsidiaries, partially offset by a \$0.8 million gain which resulted from a favorable adjustment to the rental terms of one of our leased facilities. Other loss of \$1.2 million for the three months ended September 30, 2006 included \$1.5 million of charges related to two legal settlements during this period. In addition to the \$1.5 million in legal settlements is a \$0.8 million gain on a legal settlement related to the resolution of a contingency related to our 2003 acquisition of 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.

(Benefit) Provision for Income Taxes. An income tax benefit of \$1.6 million was reported for the three months ended September 30, 2007, compared to a provision for income taxes of \$1.6 million for the three months ended September 30, 2006. Provision for incomes taxes was \$1.6 million for the nine months ended September 30, 2007, compared to \$3.9 million for the nine months ended September 30, 2006. The effective tax rate was 0.9% and (0.7)% for the three and nine months ended September 30, 2007, respectively, compared to (20)% for both the three and nine months ended September 30, 2006. The income tax benefit for the three months ended September 30, 2007 includes \$2.4 million of benefit relating to the recognition of US federal and state losses, as well as foreign losses and net operating loss (NOL) utilization. Other components of the tax provision include a state income tax provision and foreign income tax provisions for various foreign subsidiaries.

Equity Earnings in Unconsolidated Entities, Net of Tax. Equity earnings in unconsolidated entities is reported net of tax and includes our share of earnings in entities that we account for under the equity method of accounting. Equity earnings in unconsolidated entities for the three and nine months ended September 30, 2007 reflects the following: (i) our 50% interest in our newly formed joint venture with P&G in the amount of \$0.7 million and \$1.7 million, respectively, (ii) our 40% interest in Vedalab S.A. in the amount of \$178,000 and \$0.2 million, respectively, and (iii) our 49% interest in TechLab, Inc. in the amount of \$0.2 million and \$0.8 million, respectively.

Table of Contents

Net Loss. We incurred a net loss of \$180.6 million, or \$3.74 per basic and diluted common share, for the three months ended September 30, 2007, compared to a net loss of \$9.7 million, or \$0.27 per basic and diluted common share, for the three months ended September 30, 2006. We incurred net loss of \$229.0 million, or \$4.89 per basic and diluted common share, for the nine months ended September 30, 2007, compared to a net loss of \$22.9 million, or \$0.70 per basic and diluted common share, for the nine months ended September 30, 2006. The increases in net loss for the three and nine months ended September 30, 2007, compared to the three and nine months ended September 30, 2006, primarily resulted from the various factors as discussed above. See Note 6 of the accompanying consolidated financial statements for the calculation of net 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 and credit facilities 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, execute our restructuring plans, grow our business through new product introductions, business acquisitions 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. We may also access public equity and debt markets where consistent with our strategic or financial objectives.

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 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 September 30, 2007, we had cash and cash equivalents of \$153.3 million, an \$82.2 million increase from December 31, 2006. Our primary sources of cash during the nine months ended September 30, 2007 included \$301.0 million in net 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, \$324.2 million of net cash proceeds from P&G, associated with the formation of our 50/50 joint venture, approximately \$1.1 billion of cash from our refinancing activities, net of repayments related to our previous credit facilities and notes, and \$34.0 million of cash generated by operating activities. Investing activities during the nine months ended September 30, 2007 used a total of approximately \$1.3 billion of cash, net of cash acquired, primarily related to our acquisition activities. Fluctuations in foreign currencies favorably impacted our cash balance by \$6.9 million during the nine months ended September 30, 2007.

Operating Cash Flows

Net cash provided by operating activities during the nine months ended September 30, 2007 was \$34.0 million, which resulted from \$293.0 million of non-cash items, offset by our net loss of \$229.0 million and \$30.0 million of cash used to meet net working capital requirements during the period. The \$293.0 million of non-cash items included a \$169.0 million charge associated with the write-off of IPR&D in connection with our acquisition of Biosite, \$61.6 million related to depreciation and amortization and \$46.9 million related to non-cash stock-based compensation expense.

Table of Contents*Investing Cash Flows*

Our investing activities during the nine months ended September 30, 2007 utilized approximately \$1.3 billion of net cash, including \$1.6 billion used for acquisitions and transaction-related costs, net of cash acquired, \$13.4 million of cash related to minority investment activities, \$21.5 million of capital expenditures, net of proceeds from sale of equipment, a \$29.5 million increase in other assets, offset by net cash proceeds of \$324.2 million related to the formation of our 50/50 joint venture with P&G.

Significant acquisitions during the nine months ending September 30, 2007 included Biosite, QAS, Instant and First Check, which accounted for the \$1.6 billion in cash, net of cash acquired, used for acquisitions.

Financing Cash Flows

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.

On June 26, 2007, in connection with our acquisition of Biosite, we entered into a secured First Lien Credit Agreement and a secured Second Lien Credit Agreement (collectively, the Credit Agreement) with certain lenders, General Electric Capital Corporation as administrative agent and collateral agent, and certain other agents and arrangers, and certain related guaranty and security agreements. The First Lien Credit Agreement provides for term loans in the aggregate amount of \$900.0 million and, subject to our continued compliance with the First Lien Credit Agreement, a \$150.0 million revolving line of credit. The Second Lien Credit Agreement provides for term loans in the aggregate amount of \$250.0 million. As of September 30, 2007, aggregate borrowings amounted to \$41.0 million under the revolving line of credit and \$1.1 billion under the term loans. Interest expense related to our new credit facility which included the term loans and revolving line of credit for the three and nine months ended September 30, 2007, including amortized deferred costs, was \$27.5 million and \$29.2 million, respectively. As of September 30, 2007, we were in compliance with all debt covenants related to the above debt.

Simultaneously with our entry into the Credit Agreements, we terminated our existing third amended and restated credit agreement dated June 30, 2005 (the Prior Credit Agreement). We had no outstanding loans under the Prior Credit Agreement at the time it was terminated.

In addition, on June 26, 2007, we also fully repaid our 8.75% senior subordinated notes due 2012 (the Notes). The total amount repaid, including principal of \$150.0 million and a prepayment premium of \$9.3 million, was \$159.3 million. Accrued interest of \$4.8 million was also paid as part of the final settlement of these Notes and unamortized deferred financing costs of \$3.7 million were written off as a result of the repayment.

Additionally, we received proceeds from the May 14, 2007 sale of \$150.0 million principal amount of 3% convertible senior subordinated notes due 2016 (the Convertible Notes) in a private placement to qualified institutional buyers to help finance the Biosite acquisition. At the initial conversion price of \$52.30, the Convertible Notes are convertible into an aggregate 2,868,120 shares of our common stock. The conversion price is subject to adjustment one year from the date of sale if the 30 day volume-weighted average trading price of our common stock as of such date is lower than \$40.23, subject to a floor of \$40.23, or from time to time in the event of stock splits, stock dividends, recapitalizations and other similar events. The conversion price is also subject to a make-whole payment in the form of an adjustment to the conversion price in the event of a fundamental change (as defined in the Indenture). Interest accrues at 3% per annum, compounded daily, on the outstanding principal amount and is payable in arrears on May 15th and Nov 15th, which will start on November 15, 2007. Interest expense for the three and nine months ended September 30, 2007, including amortized deferred costs, was \$1.2 million and \$1.8 million, respectively.

In August 2007, we entered into interest rate swap contracts, with an effective date of September 28, 2007, that have a total notional value of \$350.0 million and have a maturity date of September 28, 2010. These interest rate swap contracts will pay us variable interest at the three-month LIBOR rate, and we will pay the counterparties a fixed rate

of 4.85%. These interest rate swap contracts were entered into to convert \$350.0 million of the \$1.3 billion variable rate term loan under the senior credit facility into fixed rate debt. Based on the terms of the interest rate swap contracts and the underlying debt, these interest rate swap contracts were determined to be effective, and thus qualify as a cash flow hedge under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. As such, any changes in the fair value of these interest rate swaps are recorded in other comprehensive income on the accompanying consolidated balance sheet until earnings are affected by the variability of cash flows.

Table of Contents

As of September 30, 2007 we had an aggregate of \$0.8 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 NOL carryforward and \$33.3 million of foreign NOL carryforward, 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 NOL carryforward amount at December 31, 2006 included approximately \$70.5 million of pre-acquisition losses at Inverness Medical Nutritionals Group, Ischemia Technologies, Inc., Ostex International, Inc. and Advantage Diagnostics Corporation and the foreign NOL 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 NOL carryforward 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.

Off-Balance Sheet Arrangements

In August 2007, we entered into interest rate swap contracts, with an effective date of September 28, 2007, that have a total notional value of \$350.0 million and have a maturity date of September 28, 2010. These interest rate swap contracts will pay us variable interest at the three-month LIBOR rate, and we will pay the counterparties a fixed rate of 4.85%. These interest rate swap contracts were entered into to convert \$350.0 million of the \$1.3 billion variable rate term loan under the senior credit facility into fixed rate debt. Based on the terms of the interest rate swap contracts and the underlying debt, these interest rate swap contracts were determined to be effective, and thus qualify as a cash flow hedge under SFAS No. 133. As such, any changes in the fair value of these interest rate swaps are recorded in other comprehensive income on the accompanying consolidated balance sheet until earnings are affected by the variability of cash flows.

Contractual Obligations

The following table summarizes our principal contractual obligations as of September 30, 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) | \$ 1,349,364 | \$ 4,885 | \$ 5,614 | \$ 115 | \$ 1,338,750 |
| Capital lease obligation | 808 | 176 | 495 | 137 | |
| Purchase obligations capital expenditures | 12,555 | 12,555 | | | |
| Purchase obligations Innovacon business (2) | 6,000 | 6,000 | | | |
| Interest on debt (3) | 40,500 | 2,823 | 9,000 | 9,000 | 19,677 |
| | \$ 1,409,227 | \$ 26,439 | \$ 15,109 | \$ 9,252 | \$ 1,358,427 |

- (1) Long-term debt obligations increased by \$1.1 billion since December 31, 2006, primarily due to our new credit facility in connection with our acquisition of Biosite, during the nine months ended September 30, 2007.

- (2) In connection with our acquisition of the Innoacon business, we are obligated to make a \$6.0 million payment for the remaining first territory business.

Table of Contents

- (3) Amounts are based on \$150.0 million, 3% convertible senior subordinated notes. Amounts exclude interest on all other debt due to variable interest rates.

As of September 30, 2007, we had contingent consideration obligations related to our acquisitions of Spectral/Source, 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 Spectral/Source, we will pay an earn-out equal to two times the consolidated revenue of Spectral/Source less \$4.0 million, if the consolidated profits before tax of Spectral/Source is at least \$0.9 million on the one year anniversary (milestone period) following the acquisition date. If consolidated profits before tax of Spectral/Source for the milestone period are less than \$0.9 million, then the amount of the payment will be equal to seven times Spectral/Source's consolidated profits before tax less \$4.0 million. The contingent consideration is payable 60% in cash and 40% in stock.

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 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 not 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. Successful development of one of the qualifying products was completed during the second quarter of 2007 for which we made a payment in the amount of \$3.7 million during the third quarter.

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.

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.

Table of Contents*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 Determine business in June 2005 from Abbott Laboratories, we entered into a manufacturing support services agreement with Abbott, whereby Abbott would continue to distribute certain of the acquired products for a period of up to 30 months following the 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 \$12.3 million and \$39.4 million, or 5% and 7%, respectively, of product sales for the three and nine months ended September 30, 2007, respectively, compared to \$14.2 million and \$38.8 million, or 9% and 9%, respectively, of product sales for the three and nine months ended September 30, 2006, respectively, which have been recorded against product sales to derive our net product sales. Our provision for sales returns and other allowances are primarily related to our consumer diagnostic business, which transferred into our joint venture. The remaining balances relate to sales made on or prior to May 17, 2007, the day prior to the effective date of the joint venture.

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 \$122.8 million and \$100.4 million, net of allowances for doubtful accounts of \$8.4 million and \$8.4 million, as of September 30, 2007 and December 31, 2006, respectively.

Table of Contents*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 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 \$136.5 million and \$78.3 million, net of a provision for excess and obsolete inventory of \$6.2 million and \$8.2 million, as of September 30, 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 September 30, 2007, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were \$243.1 million, \$1.4 billion and \$1.1 billion, 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 \$88.3 million and \$1.3 billion, respectively, as of September 30, 2007. As of September 30,

Table of Contents

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 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 September 30, 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 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

Table of Contents

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. We recorded approximately \$262.8 million of U.S. jurisdiction non-current deferred tax liabilities through purchase accounting related to the Biosite acquisition during the third quarter of 2007. Due to this change, we determined that approximately \$96.0 million of valuation allowance relating to U.S. NOLs and other U.S. deferred tax assets should be released and recorded as a reduction of goodwill in the accompanying consolidated balance sheets. Therefore, we reduced our valuation allowance to \$11.6 million as of September 30, 2007.

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 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.

Derivative Financial Instruments

We use derivative financial instruments (interest rate swap contracts) in the management of our interest rate exposure related to our senior credit facilities. We do not hold or issue derivative financial instruments for speculative purposes.

Based on the terms of the interest rate swap contracts and the underlying debt, these contracts were determined to be effective, and thus qualify as a cash flow hedge under SFAS No. 133. We record our interest rate swap contracts on the balance sheet at fair value which, at September 30, 2007 was \$0, based on the inception date of September 28, 2007. As a designated cash flow hedge, changes in the fair value of these interest rate swaps are recorded in accumulated other comprehensive income on the accompanying consolidated balance sheet until earnings are affected by the variability of cash flows.

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

Table of Contents

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.

In June 2007, the EITF reached a consensus on EITF Issue No. 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. This consensus is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier adoption is not permitted. The effect of applying the consensus will be prospective for new contracts entered into on or after that date. We do not believe that adoption of the consensus in the first quarter of 2008 will have a material impact on our consolidated financial statements.

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 7 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 is 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

Table of Contents

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 is 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;

Table of Contents

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;

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

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

our ability to manage our substantial level of indebtedness and 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; 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 September 30, 2007, our short-term investments approximated market value.

At September 30, 2007, we had a term loan in the amount of \$898.0 million and a revolving line of credit available to us of up to \$150.0 million, of which \$41.0 million was outstanding as of September 30, 2007, under our First Lien Credit Agreement. Interest on the term loan, as defined in the credit agreement, is as follows: (i) in the case of Base Rate Loans, at a rate per annum equal to the sum of the Base Rate and the Applicable Margin, each as in effect from time to time, (ii) in the case of Eurodollar Rate Loans, at a rate per annum equal to the sum of the Eurodollar Rate and the Applicable Margin, each as in effect for the applicable Interest Period, and (iii) in the case

Table of Contents

of other Obligations, at a rate per annum equal to the sum of the Base Rate and the Applicable Margin for Revolving Loans that are Base Rate Loans, each as in effect from time to time. Applicable margin with respect to Base Rate Loans is 1.00% and with respect to Eurodollar Rate Loans is 2.00%. Applicable margin ranges for our revolving line of credit with respect to Base Rate Loans is 0.75% to 1.25% and with respect to Eurodollar Rate Loans is 1.75% to 2.25%.

At September 30, 2007, we also had a term loan in the amount of \$250.0 million under our Second Lien Credit Agreement. Interest on this term loan, as defined in the credit agreement, is as follows: (i) in the case of Base Rate Loans, at a rate per annum equal to the sum of the Base Rate and the Applicable Margin, each as in effect from time to time, (ii) in the case of Eurodollar Rate Loans, at a rate per annum equal to the sum of the Eurodollar Rate and the Applicable Margin, each as in effect for the applicable Interest Period, and (iii) in the case of other Obligations, at a rate per annum equal to the sum of the Base Rate and the Applicable Margin for Base Rate Loans, as in effect from time to time. Applicable margin with respect to Base Rate Loans is 3.25% and with respect to Eurodollar Rate Loans is 4.25%.

In August 2007, we entered into interest rate swap contracts, with an effective date of September 28, 2007, that have a total notional value of \$350.0 million and have a maturity date of September 28, 2010. These interest rate swap contracts will pay us variable interest at the three-month LIBOR rate, and we will pay the counterparties a fixed rate of 4.85%. These interest rate swap contracts were entered into to convert \$350.0 million of the \$1.3 billion variable rate term loan under the senior credit facility into fixed rate debt. Based on the terms of the interest rate swap contracts and the underlying debt, these interest rate swap contracts were determined to be effective, and thus qualify as a cash flow hedge under SFAS No. 133. As such, any changes in the fair value of these interest rate swaps are recorded in other comprehensive income on the accompanying consolidated balance sheet until earnings are affected by the variability of cash flows.

Assuming no changes in our leverage ratio, which would affect the margin of the interest rates under the credit agreements, the effect of interest rate fluctuations on outstanding borrowings as of September 30, 2007 over the next twelve months is quantified and summarized as follows (in thousands):

| | Interest Expense Increase |
|---|--|
| Interest rates increase by 1 basis point | \$ 11,888 |
| Interest rates increase by 2 basis points | \$ 23,776 |

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 and nine months ended September 30, 2007, the net impact of foreign currency changes on transactions was a gain of \$1.3 million and \$2.6 million, respectively. The foreign currency gain for the nine months ended September 30, 2007 included a \$1.9 million gain on the settlement of intercompany notes. 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. During the three and nine months ended September 30, 2006, the net impact of foreign currency changes on transactions was a loss of \$0.1 million and a gain of \$3.2 million, respectively. The foreign currency gain for the nine month ending September 30, 2006 included the impact of a \$4.3 million gain resulting from the closure of our CDIL operation in Galway, Ireland.

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 49.0% for the three months ended September 30, 2007. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during the three months ended September 30, 2007, our gross margin on total net product sales would have been 49.1%, 49.4%, and 49.9%, respectively. Our gross margin on total net product sales was 46.8% for the nine months ended September 30, 2007. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates

during the nine months ended September 30, 2007, our gross margin on total net product sales would have been 47.0%, 47.6%, and 48.3%, 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 of our foreign subsidiaries, our net revenue and net loss would have been lower by approximately the following amounts (in thousands):

44

Table of Contents

| | Approximate decrease in net revenue | Approximate increase in net loss |
|---|--|---|
| If, during the three months ended September 30, 2007, the U.S. dollar was stronger by: | | |
| 1% | \$ 357 | \$ 36 |
| 5% | \$ 1,785 | \$ 182 |
| 10% | \$ 3,570 | \$ 364 |

| | Approximate decrease in net revenue | Approximate increase in net loss |
|--|--|---|
| If, during the nine months ended September 30, 2007, the U.S. dollar was stronger by: | | |
| 1% | \$ 1,378 | \$ 123 |
| 5% | \$ 6,888 | \$ 615 |
| 10% | \$ 13,776 | \$ 1,231 |

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**

Other than as set forth below, there have been no material changes in the Risk Factors described in Part I, Item 1A (Risk Factors) of our Annual Report on Form 10-K, as amended, for the year ended December 31, 2006 (the Form 10-K) or in Part II, Item 1A, Risk Factors, of any subsequent Quarterly Report on Form 10-Q.

Acquisition of HemoSense

On November 6, 2007, we completed our previously announced acquisition of HemoSense, Inc.

Pending Acquisition of Alere

On October 24, 2007, we entered into a merger agreement pursuant to which we will acquire Alere. The completion of the merger is subject to various customary closing conditions.

Alere is in the business of providing health management services to patients with chronic illnesses, a business which differs significantly from our core professional and consumer diagnostic product businesses. Although we intend to retain the senior management team and substantially all of the employees of Alere following the acquisition, we do not have substantial experience in Alere's business sector. Accordingly, we may not be able to compete in this sector as effectively as more experienced competitors.

The risk factors set forth in the Form 10-K relating to acquisitions and the integration of acquired businesses apply to our recently acquired and pending acquisitions. This includes the risk that, through acquired businesses, we may assume significant liabilities, including lawsuits or other claims. For example, HemoSense and Alere are both subject to lawsuits, including lawsuits relating to intellectual property rights. As the acquiror of HemoSense and Alere, we assume responsibility for the cost of defending these lawsuits once these transactions are completed. These lawsuits could be expensive and while we anticipate that the resolution of these lawsuits would not have a material adverse impact on our financial condition, an adverse determination could materially and adversely impact the acquired business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On July 27, 2007, we issued a total of 40,186 shares of common stock, as consideration for the acquisition of all of the capital stock of Spectral Diagnostics Private Limited and Source Diagnostics (India) Private Limited, pursuant to an exemption afforded by Section 4(2) of the Securities Act of 1933, as amended.

Table of Contents

ITEM 6. EXHIBITS

Exhibits:

| Exhibit No. | Description |
|--------------------|--|
| 10.1 | Lease Agreement between Cholestech Corporation and the BIV Group dated July 23, 2001 |
| 10.2 | Lease Agreement Addendum No. One by and between Cholestech Corporation and BIV Group dated November 19, 2004 |
| 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 |

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: November 8, 2007

/s/ DAVID TEITEL

David Teitel
Chief Financial Officer and an
authorized officer