

INVERNESS MEDICAL INNOVATIONS INC

Form 10-Q

November 07, 2008

**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, 2008**

**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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  
☐

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting  
company ☐

(Do not check if a smaller reporting company)

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 4, 2008 was 78,122,725.



**INVERNESS MEDICAL INNOVATIONS, INC.**

**REPORT ON FORM 10-Q**

**For the Quarterly Period Ended September 30, 2008**

*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, 2007, 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 52 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**

	<b>PAGE</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<b><u>Item 1. Financial Statements (unaudited):</u></b>	
<b><u>a) Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2008 and 2007</u></b>	3
<b><u>b) Consolidated Balance Sheets as of September 30, 2008 and December 31, 2007 (Restated)</u></b>	4
<b><u>c) Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2008 and 2007</u></b>	5
<b><u>d) Notes to Consolidated Financial Statements</u></b>	6
<b><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	32
<b><u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u></b>	54
<b><u>Item 4. Controls and Procedures</u></b>	55
<b><u>PART II. OTHER INFORMATION</u></b>	
<b><u>Item 1. Legal Proceedings</u></b>	56
<b><u>Item 1A. Risk Factors</u></b>	56
<b><u>Item 6. Exhibits</u></b>	57
<b><u>SIGNATURE</u></b>	58
<b><u>EX-31.1 SECTION 302 CERTIFICATION OF CEO</u></b>	
<b><u>EX-31.2 SECTION 302 CERTIFICATION OF CFO</u></b>	
<b><u>EX-32.1 SECTION 906 CERTIFICATION OF CEO AND CFO</u></b>	

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)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Net product sales	\$ 305,266	\$ 226,128	\$ 918,484	\$ 531,132
Services revenue	127,768	2,440	272,200	3,389
<b>Net product sales and services revenue</b>	433,034	228,568	1,190,684	534,521
License and royalty revenue	5,766	9,068	21,476	17,059
<b>Net revenue</b>	438,800	237,636	1,212,160	551,580
Cost of net product sales	153,103	125,071	470,160	288,931
Cost of services revenue	55,906	133	119,876	169
Cost of license and royalty revenue	1,643	2,134	7,484	7,504
<b>Cost of net revenue</b>	210,652	127,338	597,520	296,604
<b>Gross profit</b>	228,148	110,298	614,640	254,976
Operating expenses:				
Research and development	25,693	20,530	86,426	44,649
Purchase of in-process research and development		169,000		169,000
Sales and marketing	104,607	48,536	281,297	104,847
General and administrative	84,601	28,707	215,390	119,161
Total operating expenses	214,901	266,773	583,113	437,657
<b>Operating income (loss)</b>	13,247	(156,475)	31,527	(182,681)
Interest expense, including amortization and write-off of deferred financing costs (Note 11)	(23,600)	(29,041)	(78,762)	(56,238)
Other income (expense), net	(1,152)	2,143	(5,389)	8,822
<b>Loss before benefit for income taxes</b>	(11,505)	(183,373)	(52,624)	(230,097)
(Benefit) provision for income taxes	(4,696)	(1,645)	(13,274)	1,550
Equity earnings of unconsolidated entities, net of tax (Note 10)	3,150	1,116	1,169	2,666
<b>Net loss</b>	(3,659)	(180,612)	(38,181)	(228,981)
Preferred stock dividends	(5,393)		(8,500)	

<b>Net loss available to common stockholders</b>	\$ (9,052)	\$ (180,612)	\$ (46,681)	\$ (228,981)
<b>Net loss per common share basic and diluted (Note 5)</b>	\$ (0.12)	\$ (3.74)	\$ (0.60)	\$ (4.89)
<b>Weighted average common shares basic and diluted (Note 5)</b>	77,995	48,256	77,630	46,787

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, 2008 (unaudited)	December 31, 2007 (restated)
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 154,170	\$ 414,732
Restricted cash	3,593	141,869
Marketable securities	1,994	2,551
Accounts receivable, net of allowances of \$9,248 at September 30, 2008 and \$12,167 at December 31, 2007	268,373	163,380
Inventories, net	196,646	148,231
Deferred tax assets	23,534	18,170
Income tax receivable	9,554	5,256
Prepaid expenses and other current assets	68,012	58,785
<b>Total current assets</b>	725,876	952,974
Property, plant and equipment, net	287,272	267,880
Goodwill	3,060,044	2,148,850
Other intangible assets with indefinite lives	43,116	43,097
Core technology and patents, net	470,028	432,583
Other intangible assets, net	1,217,164	869,644
Deferred financing costs, net and other non-current assets	47,013	51,747
Investments in unconsolidated entities	69,421	77,753
Marketable securities	805	20,432
Deferred tax assets	22,439	15,799
<b>Total assets</b>	\$ 5,943,178	\$ 4,880,759
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Current portion of long-term debt	\$ 19,427	\$ 20,320
Current portion of capital lease obligations	578	776
Accounts payable	108,470	72,061
Accrued expenses and other current liabilities	256,179	174,935
Payable to joint venture	158	10,816
<b>Total current liabilities</b>	384,812	278,908
<b>Long-term liabilities:</b>		
Long-term debt, net of current portion	1,504,720	1,366,395
Capital lease obligations, net of current portion	790	358
Deferred tax liabilities	442,446	326,128
Deferred gain on joint venture	291,058	293,078
Other long-term liabilities	51,876	29,225

<b>Total long-term liabilities</b>	2,290,890	2,015,184
<b>Commitments and contingencies (Note 17)</b>		
<b>Stockholders' equity:</b>		
Series B preferred stock, \$0.001 par value (liquidation preference, \$733,035)		
Authorized: 2,300 shares		
Issued and outstanding: 1,833 shares	666,387	
Common stock, \$0.001 par value		
Authorized: 150,000 shares		
Issued and outstanding: 78,084 shares at September 30, 2008 and 76,784 shares at December 31, 2007	78	77
Additional paid-in capital	3,003,467	2,937,143
Accumulated deficit	(410,003)	(371,822)
Accumulated other comprehensive income	7,547	21,269
<b>Total stockholders' equity</b>	<b>3,267,476</b>	<b>2,586,667</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 5,943,178</b>	<b>\$ 4,880,759</b>

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)

	<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (38,181)	\$ (228,981)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Interest expense related to amortization and write-off of deferred financing costs	4,432	9,549
Non-cash stock-based compensation expense	19,716	46,926
Charge for in-process research and development		169,000
Impairment of inventory	3,108	
Impairment of long-lived assets	19,472	
Loss on sale of fixed assets	241	156
Equity earnings of unconsolidated entities	(1,169)	(3,113)
Interest in minority investments	167	1,849
Depreciation and amortization	194,203	61,604
Deferred and other non-cash income taxes	(28,322)	7,046
Other non-cash items	3,779	31
Changes in assets and liabilities, net of acquisitions:		
Accounts receivable, net	(33,657)	41,684
Inventories, net	(39,767)	(7,104)
Prepaid expenses and other current assets	(4,657)	(21,851)
Accounts payable	22,154	(6,735)
Accrued expenses and other current liabilities	(11,418)	(30,734)
Other non-current liabilities	4,210	(5,302)
<b>Net cash provided by operating activities</b>	<b>114,311</b>	<b>34,025</b>
<b>Cash Flows from Investing Activities:</b>		
Purchases of property, plant and equipment	(47,014)	(21,711)
Proceeds from sale of property, plant and equipment	241	170
Cash paid for acquisitions and transactional costs, net of cash acquired	(614,175)	(1,590,107)
Cash received, net of cash paid, from formation of joint venture		324,170
Cash received from (paid for) investments in minority interests and marketable securities	11,800	(13,446)
Increase in other assets	(8,558)	(29,509)
<b>Net cash used in investing activities</b>	<b>(657,706)</b>	<b>(1,330,433)</b>
<b>Cash Flows from Financing Activities:</b>		
Decrease in restricted cash	138,219	
Issuance costs associated with preferred stock	(351)	
Cash paid for financing costs	(986)	(38,100)
Proceeds from issuance of common stock, net of issuance costs	18,566	300,901

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Net (repayments) proceeds on long-term debt	(10,680)	1,131,088
Net proceeds from revolving lines-of-credit	138,270	
Repayments of notes payable		(22,326)
Tax benefit on exercised stock options	420	625
Principal payments of capital lease obligations	(916)	(427)
<b>Net cash provided by financing activities</b>	<b>282,542</b>	<b>1,371,761</b>
Foreign exchange effect on cash and cash equivalents	291	6,888
Net (decrease) increase in cash and cash equivalents	(260,562)	82,241
Cash and cash equivalents, beginning of period	414,732	71,104
<b>Cash and cash equivalents, end of period</b>	<b>\$ 154,170</b>	<b>\$ 153,345</b>
<b>Supplemental Disclosure of Non-cash Activities:</b>		
Fair value of stock issued for acquisitions	\$ 673,803	\$ 357,346
Fair value of stock options exchanged	\$ 20,973	\$ 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, 2007 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 April 29, 2008. 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, 2007.

Certain reclassifications of prior period amounts have been made to conform to current period presentation. These reclassifications had no effect on net loss or stockholders' equity.

**(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, 2008, 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):

	<b>September 30, 2008</b>	<b>December 31, 2007</b>
Raw materials	\$ 49,464	\$ 45,111
Work-in-process	40,502	40,184
Finished goods	106,680	62,936
	<b>\$ 196,646</b>	<b>\$ 148,231</b>

**(4) Stock-based Compensation**

In accordance with Statement of Financial Accounting Standards (SFAS) No. 123-R, *Share-Based Payment*, we recorded stock-based compensation expense in our consolidated statements of operations of \$7.0 million (\$5.6 million, net of tax) and \$19.7 million (\$15.5 million, net of tax) and \$3.3 million (\$2.3 million, net of tax) and \$52.2 million (\$49.0 million, net of tax) for the three and nine-month periods ending September 30, 2008 and 2007, respectively, as follows (in thousands):

	<b>Three Months Ended September 30, 2008</b>	<b>2007</b>	<b>Nine Months Ended September 30, 2008</b>	<b>2007</b>
Cost of sales	\$ 365	\$ 119	\$ 999	\$ 317
Research and development	1,118	612	3,437	1,301
Sales and marketing	1,267	351	3,275	1,043
General and administrative	4,215	2,201	12,005	49,535
	<b>\$ 6,965</b>	<b>\$ 3,283</b>	<b>\$ 19,716</b>	<b>\$ 52,196</b>

The nine months ended September 30, 2007 included a \$45.2 million charge associated with stock option acceleration and conversion in connection with our acquisition of Biosite Incorporated, or Biosite.

**Table of Contents**

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

We report excess tax benefits from the exercise of stock options as financing cash flows. For the three months ended September 30, 2008 and 2007, there was \$0.1 million and \$0.3 million, respectively, of excess tax benefits generated from option exercises. For the nine months ended September 30, 2008 and 2007, there was \$0.4 million and \$0.6 million, 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 generally 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. We use a Black-Scholes option pricing model to calculate the grant-date fair value of options. The fair value of the stock options granted during the three and nine-month periods ended September 30, 2008 and 2007 was calculated using the following weighted-average assumptions:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
<b><u>Stock Options:</u></b>				
Risk-free interest rate	3.14%	4.45%	2.80% - 3.14%	4.45% - 5.00%
Expected dividend yield				
Expected term	5.19 years	6.25 years	5.19 years	6.25 years
Expected volatility	37.80%	43.83%	37.00% - 38.96%	43.83%

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
<b><u>Employee Stock Purchase Plan:</u></b>				
Risk-free interest rate	2.13%	4.17%	2.13% - 3.32%	4.17%
Expected dividend yield				
Expected term	184 days	184 days	184 days	184 days
Expected volatility	53.87%	69.49%	43.31% - 53.87%	69.49%

A summary of the stock option activity for the nine months ended September 30, 2008 is as follows (in thousands, except price per share and contractual term):

	<b>Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term</b>	<b>Aggregate Intrinsic value</b>
Options outstanding, January 1, 2008	7,836	\$ 31.42		
Exchanged	1,820	\$ 31.97		
Granted	1,304	\$ 39.74		
Exercised	(688)	\$ 18.28		
Canceled/expired /forfeited	(296)	\$ 39.73		
Options outstanding, September 30, 2008	9,976	\$ 33.27	6.78 years	\$ 47,713
Options exercisable, September 30, 2008	5,620	\$ 25.00	5.12 years	\$ 45,955

The weighted average grant-date fair value under a Black-Scholes option pricing model of options granted during the nine months ended September 30, 2008 and 2007 was \$11.80 per share and \$21.57 per share, respectively. The total intrinsic value of options exercised during the three and nine months ended September 30, 2008 was \$1.8 million and \$16.9 million, respectively.

As of September 30, 2008, there was \$68.8 million of total unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining weighted-average vesting period of 1.75 years.

**Table of Contents**

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

**(5) 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):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
<b>Net loss per common share basic and diluted:</b>				
<b>Numerator:</b>				
Net loss	\$ (3,659)	\$ (180,612)	\$ (38,181)	\$ (228,981)
Less: Preferred stock dividends	5,393		8,500	
Net loss available to common stockholders	\$ (9,052)	\$ (180,612)	\$ (46,681)	\$ (228,981)
<b>Denominator:</b>				
Weighted average common shares outstanding	77,995	48,256	77,630	46,787
Net loss per common share basic and diluted	\$ (0.12)	\$ (3.74)	\$ (0.60)	\$ (4.89)

We had the following potential dilutive securities outstanding on September 30, 2008: options and warrants to purchase an aggregate of 10.4 million shares of common stock at a weighted average exercise price of \$32.72 per share, \$150.0 million of 3% senior subordinated convertible notes, convertible at \$43.98 per share, and 1.8 million shares of our Series B convertible preferred stock, convertible under certain circumstances at \$69.32 per share. These potential dilutive securities were not included in the computation of diluted net loss per common share for the three and nine months ended September 30, 2008 because the effect of including such potential dilutive securities would be anti-dilutive.

We had the following potential dilutive securities outstanding on September 30, 2007: options and warrants to purchase an aggregate of 7.0 million shares of common stock at a weighted average exercise price of \$27.56 per share and \$150.0 million of 3% convertible notes, convertible at \$52.30 per share. These potential dilutive securities were not included in the computation of diluted net loss per common share for the three and nine months ended September 30, 2007 because the effect of including such potential dilutive securities would be anti-dilutive.

**(6) Preferred Stock**

As of September 30, 2008, we had 5.0 million shares of preferred stock, \$0.001 par value, authorized, of which 2.3 million shares were designated as Series B Convertible Perpetual Preferred Stock, or Series B preferred stock. On May 8, 2008, in connection with our acquisition of Matria Healthcare Inc., or Matria, we issued 1.8 million shares of the Series B preferred stock with a fair value of approximately \$657.9 million (Note 8(a)(i)).

Each share of Series B preferred stock, which has a liquidation preference of \$400.00 per share, is convertible, at the option of the holder and only upon certain circumstances, into 5.7703 shares of our common stock, plus cash in lieu of fractional shares. The initial conversion price is \$69.32 per share, subject to adjustment upon the occurrence of

certain events, but will not be adjusted for accumulated and unpaid dividends. Upon a conversion of shares of the Series B preferred stock, we may, at our option, satisfy the entire conversion obligation in cash or through a combination of cash and common stock. There were no conversions as of September 30, 2008.

Generally, the shares of Series B preferred stock are convertible, at the option of the holder, if during any calendar quarter beginning with the second calendar quarter after the issuance date of the Series B preferred stock, if the closing sale price of our common stock for each of 20 or more trading days within any period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the conversion price per share of common stock in effect on the last trading day of the immediately preceding calendar quarter. In addition, the shares of Series B preferred stock are convertible, at the option of the holder, in certain other circumstances, including those relating to the trading price of the Series B preferred stock and upon the occurrence of certain fundamental changes or major corporate transactions. We also have the right, under certain circumstances relating to the trading price of our common stock, to force conversion of the Series B preferred stock. Depending on the timing of any such forced conversion, we may have to make certain payments relating to foregone dividends,



**Table of Contents**

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

which payments we can make, at our option, in the form of cash, shares of our common stock, or a combination of cash and shares of our common stock.

Each share of Series B preferred stock accrues dividends at \$12.00, or 3%, per annum, payable quarterly on January 15, April 15, July 15 and October 15 of each year, commencing following the first full calendar quarter after the issuance date. Dividends on the Series B preferred stock are cumulative from the date of issuance. For the three and nine months ended September 30, 2008, Series B preferred stock dividends amounted to \$5.4 million and \$8.5 million, respectively, which reduced earnings available to common stockholders for purposes of calculating loss per share in both periods in 2008 (Note 5). Accrued dividends are payable only if declared by our board of directors and, upon conversion by the Series B preferred stockholder, holders will not receive any cash payment representing accumulated dividends. If our board of directors declares a dividend payable, we have the right to pay the dividends in cash, shares of common stock, additional shares of Series B preferred stock or a similar convertible preferred stock or any combination thereof.

On September 15, 2008, the board of directors declared a dividend of \$4.77 per share on the Series B preferred stock. The dividend was paid in shares of Series B preferred stock in an amount per share of Series B preferred stock equal to the quotient of (a) \$4.77 divided by (b) 97% of the average of the volume-weighted average price per share of the Series B preferred stock on the American Stock Exchange for each of the five consecutive trading days ending on the second trading day immediately prior to the record date of the dividend. We paid cash in lieu of any fractional shares resulting from the dividend. The dividend was paid on October 15, 2008 to holders of record of Series B preferred stock at the close of business on October 1, 2008. This was the first dividend declared and paid on the Series B preferred stock, and such payment covered the amount of all dividends accrued from May 9, 2008, the original issuance date of the Series B preferred stock, through September 30, 2008. As of September 30, 2008, 1.8 million shares of Series B preferred stock are issued and outstanding.

The holders of Series B preferred stock have liquidation preferences over the holders of the Company's common stock and other classes of stock, if any, outstanding at the time of liquidation. Upon liquidation, the holders of outstanding Series B preferred stock would receive an amount equal to \$400.00 per share of Series B preferred stock, plus any accumulated and unpaid dividends. As of September 30, 2008, the liquidation preference of the outstanding Series B preferred stock was \$733.0 million. The holders of the Series B preferred stock have no voting rights, except with respect to matters affecting the Series B preferred stock (including the creation of a senior preferred stock).

We evaluated the terms and provisions of our Series B preferred stock to determine if it qualified for derivative accounting treatment under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. Based on our evaluation, these securities do not qualify for derivative accounting under SFAS No. 133.

**(7) 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, 2008, we generated a comprehensive loss of \$23.6 million and \$51.9 million, respectively, and for the three and nine months ended September 30, 2007, we generated a comprehensive loss of \$174.0 million and \$217.8 million, respectively.

**(8) Business Combinations**

We account for acquired businesses using the purchase method of accounting as prescribed by SFAS No. 141, *Business Combinations*. Under the purchase method, the operating results of an acquired business are included in our consolidated financial statements starting from the consummation date of the acquisition. In addition, the assets acquired and liabilities assumed must be recorded at the date of acquisition at their respective estimated fair values, with any excess of the purchase price over the estimated fair values of the net assets acquired recorded as goodwill.



**Table of Contents**

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

Significant judgment is required in estimating the fair value of intangible assets and in assigning their respective useful lives. The fair value estimates are based on available historical information and on future expectations and assumptions deemed reasonable by management, but are inherently uncertain.

We generally employ the income method to estimate the fair value of intangible assets, which is based on forecasts of the expected future cash flows attributable to the respective assets. Significant estimates and assumptions inherent in the valuations reflect a consideration of other marketplace participants, and include the amount and timing of future cash flows (including expected growth rates and profitability), the underlying product life cycles, economic barriers to entry, a brand's relative market position and the discount rate applied to the cash flows. Unanticipated market or macroeconomic events and circumstances may occur, which could affect the accuracy or validity of the estimates and assumptions.

Other significant estimates associated with the accounting for acquisitions include exit costs. 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. Provided certain criteria are met, the estimated costs associated with these restructuring activities are treated as assumed liabilities, consistent with the guidance of Emerging Issue Task Force (EITF) Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination*. Our estimates and assumptions associated with these restructuring activities may change as we execute approved plans. Decreases to the estimated costs are generally recorded as an adjustment to goodwill. Increases to the estimates are generally recorded as an adjustment to goodwill during the purchase price allocation period (generally within one year of the acquisition date) and as operating expenses thereafter.

Any common stock issued in connection 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*.

Some of our acquisitions have involved an exchange of employee stock options and restricted stock awards. Accordingly, we have accounted for these exchanges within a purchase business combination under the guidance of SFAS No. 123-R. In general, to the extent that the fair value of our awards approximate the fair value of the acquired-company awards, the fair value of the awards has been recognized as a component of the purchase price. The fair value of unvested or partially-vested awards is allocated between the vested and unvested portions of the awards. The fair value of the unvested portion is deducted from the purchase price and recognized as compensation cost as that portion vests.

*(a) Acquisitions in 2008*

*(i) Acquisition of Matria*

On May 9, 2008, we acquired Matria, a national provider of health improvement, disease management and high-risk pregnancy management programs and services. The preliminary aggregate purchase price was \$819.6 million, which consisted of \$141.3 million in cash, Series B convertible preferred stock with a fair value of approximately \$657.9 million, \$17.3 million of fair value associated with Inverness employee stock options exchanged as part of the transaction and \$3.0 million for direct acquisition costs. In addition, we assumed and immediately repaid debt totaling approximately \$279.2 million. The operating results of Matria are included in our health management reporting unit and business segment.

A summary of the preliminary purchase price allocation for this acquisition is as follows (in thousands):

Current assets	\$ 103,912
Property, plant and equipment	24,465
Goodwill	829,237
Intangible assets	325,385



**Table of Contents**

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

Other non-current assets	21,467
Total assets acquired	1,304,466
Current liabilities	355,575
Non-current liabilities	129,286
Total liabilities assumed	484,861
Net assets acquired	819,605
Less:	
Acquisition costs	3,009
Fair value of Series B convertible preferred stock issued (1,787,834 shares)	657,923
Fair value of stock options exchanged (1,490,655 options)	17,334
Cash consideration	\$ 141,339

We expect that all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	<b>Amount</b>	<b>Amortizable Life</b>
Core technology	\$ 31,000	3 years
Database	25,000	10 years
Trade names	1,185	5 months
Customer relationships	253,000	13 years
Non-compete agreements	15,200	0.75-3 years
Total intangible assets with finite lives	\$ 325,385	

(ii) Acquisition of BBI

On February 12, 2008, we acquired BBI Holdings Plc, or BBI, a publicly-traded company headquartered in the United Kingdom that specializes in the development and manufacture of non-invasive lateral flow tests and gold reagents. The preliminary aggregate purchase price was \$163.2 million, which consisted of \$138.6 million in cash, including \$14.7 million of cash paid for our previously owned shares of BBI common stock, common stock with an aggregate fair value of \$14.4 million, \$6.6 million for direct acquisition costs and \$3.6 million of fair value associated with Inverness employee stock options exchanged as part of the transaction. The operating results of BBI are included in our professional and consumer diagnostic products reporting units and business segments.

A summary of the preliminary purchase price allocation for this acquisition is as follows (in thousands):

Current assets	\$ 22,801
Property, plant and equipment	7,603
Goodwill	86,739
Intangible assets	90,201

Other non-current assets	3,001
Total assets acquired	210,345
Current liabilities	14,993
Non-current liabilities	32,141
Total liabilities assumed	47,134
Net assets acquired	163,211
Less:	
Acquisition costs	6,581
Fair value of common stock issued (251,085 shares)	14,397
Fair value of stock options/awards exchanged (329,612 options/25,626 awards)	3,639
Cash consideration	\$ 138,594

**Table of Contents**

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

We expect that all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	<b>Amount</b>	<b>Amortizable Life</b>
Core technology	\$ 28,043	15-20 years
Trade names and other intangible assets	16,180	10-25 years
Customer relationships	45,978	7-25 years
 Total intangible assets with finite lives	 \$ 90,201	

(iii) Acquisition of Panbio

On January 7, 2008, we acquired Panbio Limited, or Panbio, an Australian publicly-traded company headquartered in Brisbane, Australia, that develops and manufactures diagnostic tests for use in the diagnosis of a broad range of infectious diseases. The preliminary aggregate purchase price was \$36.5 million, which consisted of \$35.9 million in cash and \$0.6 million for direct acquisition costs. In June 2008, we sold certain assets totaling \$1.8 million related to a particular product line. The sale of these assets, at their acquisition date fair values, is reflected in the preliminary purchase price allocation. The operating results of Panbio are included in our professional diagnostic products reporting unit and business segment.

A summary of the preliminary purchase price allocation for this acquisition is as follows (in thousands):

Current assets	\$ 12,835
Property, plant and equipment	2,080
Goodwill	13,369
Intangible assets	17,717
Other non-current assets	246
 Total assets acquired	 46,247
 Current liabilities	 2,928
Non-current liabilities	6,810
 Total liabilities assumed	 9,738
 Net assets acquired	 36,509
Less:	
Acquisition costs	566
 Cash consideration	 \$ 35,943

We expect that all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	<b>Amount</b>	<b>Amortizable Life</b>
Core technology	\$ 4,154	5-7 years
Trade name	2,382	10 years
Customer relationships	11,181	17-25 years
Total intangible assets with finite lives	\$ 17,717	



**Table of Contents**

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

## (iv) Other acquisitions in 2008

During the first nine months of 2008, we acquired the following assets and businesses for a preliminary purchase price of \$34.0 million, in which we paid \$26.3 million in cash, \$0.8 million in direct acquisition costs, and accrued contingent consideration and milestone payments totaling \$6.9 million:

Certain assets from Mochida Pharmaceutical Co., Ltd, or Mochida. As part of the acquisition of certain assets, Mochida transferred the exclusive distribution rights in Japan for certain Osteomark products (Acquired April 2008).

Privately-owned provider of care and health management services (Acquired July 2008).

Vision Biotech Pty Ltd, or Vision, located in Cape Town, South Africa, a privately-owned distributor of rapid diagnostic products predominantly to the South African marketplace (Acquired September 2008).

Global Diagnostics CC, or Global, located in Johannesburg, South Africa, a privately-owned contract manufacturer and distributor of high quality rapid diagnostic tests predominantly to the South African marketplace (Acquired September 2008).

DiaTeam Diagnostika, or DiaTeam, located in Linz, Austria, a privately-owned distributor of high quality rapid diagnostic tests predominantly to the Austrian marketplace (Acquired September 2008).

A summary of the preliminary purchase price allocation for these acquisitions is as follows (in thousands):

Current assets	\$ 6,549
Property, plant and equipment	424
Goodwill	7,726
Intangible assets	31,105
 Total assets acquired	 45,804
 Current liabilities	 4,191
Non-current liabilities	7,632
 Total liabilities assumed	 11,823
 Net assets acquired	 33,981
Less:	
Acquisition costs	809
Accrued earned milestone and contingent consideration	6,893
 Cash consideration	 \$ 26,279

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Core technology	\$ 1,867	10 years

Trade names	1,353	10 years
Customer relationships	26,792	3.5-30 years
Non-compete agreements	264	2.67-5 years
Manufacturing know-how	829	5 years
Total intangible assets	\$ 31,105	

Mochida, Vision, Global and DiaTeam are included in our professional diagnostic products reporting unit and business segment; and the healthcare acquisition is included in our health management reporting unit and business segment. Goodwill has been recognized in the Vision, Global and DiaTeam transactions and amounted to approximately \$7.7 million. Goodwill related to these acquisitions is not deductible for tax purposes.

**Table of Contents**

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

*(b) Acquisitions in 2007*

During the year ended December 31, 2007, we acquired the following businesses for an aggregate purchase price of \$3.2 billion, in which we paid \$2.2 billion in cash, issued 14,613,591 shares of our common stock with an aggregate fair value of \$790.8 million, \$135.0 million of fair value associated with employee stock options and restricted stock awards which were exchanged as part of the transaction, incurred \$81.5 million in direct acquisition costs and accrued milestone payments totaling \$14.8 million:

ParadigmHealth, Inc., or ParadigmHealth, located in Upper Saddle River, New Jersey, a privately-owned leading provider of precise medical management to provide optimal health outcomes for acutely ill and clinically complex patients (Acquired December 2007).

Redwood Toxicology Laboratories, Inc., or Redwood, located in Santa Rosa, California, a privately-owned drugs of abuse diagnostics and testing company (Acquired December 2007).

Matritech, Inc., or Matritech, located in Newton, Massachusetts and Freiburg, Germany, a biotechnology company principally engaged in the development, manufacturing, marketing, distribution and licensing of cancer diagnostic technologies and products (Acquired December 2007).

90.91% share in Biosystems S.A., or Biosystems, located in Cali and Bogota, Colombia, a distributor of diagnostics tests, instruments and reagents throughout Colombia (Acquired December 2007). In October 2008, we acquired the remaining 9.09% interest in Biosystems.

Aska Diagnostic, Inc., or Aska, located in Tokyo, Japan, a distributor of professional diagnostic products in Japan (Acquired December 2007).

Alere Medical, Inc., or Alere, located in Reno, Nevada, a privately-held leading provider of care and health management services (Acquired November 2007).

HemoSense, Inc., or HemoSense, located in San Jose, California, a publicly-traded developer and marketer of point-of-care testing products for therapeutic drug monitoring (Acquired November 2007).

the assets of Akubio, a research company located in Cambridge, England (Acquired October 2007).

Bio-Stat Healthcare Group, or Bio-Stat, located in Cheshire, United Kingdom, a privately-owned distributor of core laboratory and point-of-care diagnostic testing products to the U.K. marketplace (Acquired October 2007).

Cholestech Corporation, or Cholestech, located in Haywood, California, a publicly-traded leading provider of diagnostic tools and information for immediate risk assessment and therapeutic monitoring of heart disease and inflammatory disorders (Acquired September 2007).

52.45% share in Diamics, Inc., or Diamics, located in Novato, California, a developer of molecular-based cancer screening and diagnostic systems (Acquired July 2007).

Spectral Diagnostics Private Limited and its affiliate Source Diagnostics (India) Private Limited, or Spectral/Source, located in New Delhi and Shimla, India, a distributor of professional diagnostic products in India (Acquired July 2007).

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Biosite, located in San Diego, California, a publicly-traded global medical diagnostic company utilizing a biotechnology approach to create products for the diagnosis of critical diseases and conditions (Acquired June 2007).

Quality Assured Services, Inc., or QAS, located in Orlando, Florida, a privately-owned provider of diagnostic home tests and services in the U.S. marketplace (Acquired June 2007).

Orange Medical, or Orange, located in Tilburg, The Netherlands, a manufacturer and marketer of rapid diagnostic products to the Benelux marketplace (Acquired May 2007).

**Table of Contents**

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

Instant Technologies, Inc., or Instant, located in Norfolk, Virginia a privately-owned distributor of rapid drugs of abuse diagnostic products used in the workplace, criminal justice and other testing markets (Acquired March 2007).

First Check Diagnostics LLC, or First Check, located in Lake Forrest, California, a privately-held diagnostics company in the field of home testing for drugs of abuse, including marijuana, cocaine, methamphetamines and opiates (Acquired January 2007).

Promesan S.r.l., or Promesan, located in Milan, Italy, a distributor of point-of-care diagnostic testing products to the Italian marketplace (Acquired January 2007).

Gabmed GmbH, or Gabmed, located in Nettetel, Germany, a distributor of point-of-care diagnostic testing products in the German marketplace (Acquired January 2007).

the assets of Nihon Schering K.K., or NSKK, located in Japan, a diagnostic distribution business (Acquired January 2007).

Med-Ox Chemicals Limited, or Med-Ox, located in Ottawa, Canada, a distributor of professional diagnostic testing products in the Canadian marketplace (Acquired January 2007).

A summary of the preliminary purchase price allocation for these acquisitions is as follows (in thousands):

Current assets	\$ 538,672
Property, plant and equipment	175,044
Goodwill	1,708,899
Intangible assets	1,258,985
In-process research and development	173,826
Other non-current assets	128,275
 Total assets acquired	 3,983,701
 Current liabilities	 209,695
Non-current liabilities	542,234
 Total liabilities assumed	 751,929
 Net assets acquired	 3,231,772
Less:	
Acquisition costs	81,546
Cash settlement of vested stock options	51,503
Non-cash income tax benefits on stock options	2,574
Accrued earned milestone and notes payable	14,783
Fair value of common stock issued (14,613,591 shares)	790,784
Fair value of stock options and awards exchanged (2,248,566 options/awards)	83,519
 Cash consideration	 \$ 2,207,063

In connection with our acquisition of Biosite in 2007, we acquired various in-process research and development, or 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 U.S. Food and Drug Administration, or 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 we acquired in connection with the Biosite acquisition (in thousands):

15

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**Table of Contents**

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

				<b>Discount Rate Used in Estimating</b>	<b>Year of Expected</b>
<b>Company/ Year Assets</b>	<b>Purchase Price</b>	<b>IPR&amp;D (1)</b>	<b>Programs Acquired</b>	<b>Cash Flows(1)</b>	<b>Launch</b>
Biosite/2007	\$ 1,800,000	\$ 13,000	Triage Sepsis Panel	15%	2008-2010
		156,000	Triage NGAL	15%	2008-2010
		\$ 169,000			

(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.

NSKK and Promesan are included in our professional and consumer diagnostic products reporting units and business segments; ParadigmHealth, Redwood, Matritech, Alere, HemoSense, Aska, Biosystems, Bio-Stat, Akubio, Spectral/Source, Orange, QAS, Instant, Gabmed and Med-Ox were originally included in our professional diagnostic products reporting unit and business segment (as noted in Note 15, ParadigmHealth, Alere and QAS have been reclassified to our health management reporting unit and business segment); Cholestech and Biosite are included in our cardiology reporting unit of our professional diagnostic products business segment; and First Check is included in our consumer diagnostic products reporting unit and business segment. Biosystems and Diamics are consolidated and included in our professional diagnostic products reporting unit and business segment. The 9.09% minority interest in Biosystems is recorded in other long-term liabilities on our consolidated balance sheet at December 31, 2007. In October 2008, we purchased the remaining 9.09% interest in Biosystems. Goodwill related to these acquisitions, with the exception of Matritech and First Check, is not deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	<b>Amount</b>	<b>Amortizable Life</b>
Core technology	\$ 362,888	1-13.5 years
Supplier relationships	3,882	15 years
Trademarks	125,954	0.75-10.5 years
License agreements	1,275	15 years
Customer relationships	744,257	1.5-26 years
Non-compete agreements	13,241	0.5-4 years
Internally-developed software	7,250	7-10 years
Total intangible assets with finite lives	1,258,747	
Trademarks	238	N/A
Total intangible assets with indefinite lives	238	



Total intangible assets \$ 1,258,985

*(c) 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 costs associated with the 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 refined. The following table summarizes the liabilities established for exit activities related to our acquisitions (in thousands):

	<b>Severance Related</b>	<b>Facility And Other</b>	<b>Total Exit Activities</b>
Balance, December 31, 2007	\$ 14,579	\$ 1,898	\$ 16,477
Acquisitions	19,981	4,143	24,124
Payments and other	(18,601)	(565)	(19,166)
Currency adjustments	(385)	77	(308)
Balance, September 30, 2008	\$ 15,574	\$ 5,553	\$ 21,127

**Table of Contents**

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

In conjunction with our June 2007 acquisition of Biosite, we implemented an integration plan to improve operating 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. Since the inception of the plan, we recorded \$15.4 million in exit costs, of which \$15.1 million relates to change in control and severance costs to involuntarily terminate employees and \$0.3 million relates to facility and other exit costs. As of September 30, 2008, \$2.5 million in exit costs remain unpaid.

During 2007, we formulated restructuring plans in connection with our acquisition of Cholestech, consistent with our acquisition strategy to realize operating efficiencies and cost savings. Additionally, in March 2008, we announced plans to close the Cholestech facility in Hayward, California. We are transitioning the manufacturing of the related products to the Biosite facility in San Diego, California and have transitioned the sales and distribution of the products to our newly-formed shared service center in Orlando, Florida. Since inception of the plans, we recorded \$9.1 million in exit costs, of which \$6.4 million relates to executive change in control agreements and severance costs to involuntarily terminate employees and \$2.7 million relates to facility exit costs. As of September 30, 2008, \$6.8 million in exit costs remain unpaid.

In conjunction with our acquisition of HemoSense, we formulated restructuring plans during 2007 to realize operating efficiencies and cost savings. Additionally, in March 2008, we announced plans to close the HemoSense facility in San Jose, California. We are transitioning the manufacturing of the related products to the Biosite facility in San Diego, California and have transitioned the sales and distribution of the products to our newly-formed shared service center in Orlando, Florida. Since inception of the plans, we recorded \$1.5 million in exit costs, of which \$1.3 million relates to severance costs to terminate employees and \$0.2 million relates to facility and other exit costs. As of September 30, 2008, \$0.7 million in exit costs remain unpaid.

In conjunction with our acquisition of Matritech, we formulated a plan to exit the leased facility of Matritech in Newton, Massachusetts and recorded \$1.4 million in facility exit costs. As of September 30, 2008, \$1.2 million of the facility exit costs remain unpaid.

In conjunction with our acquisition of ParadigmHealth, we recorded \$1.8 million in severance costs. As of September 30, 2008, \$1.0 million in severance costs remain unpaid.

In conjunction with our acquisition of Panbio, we formulated a restructuring plan to realize efficiencies and cost savings. In February 2008, we agreed upon a plan to close Panbio's facility located in Columbia, Maryland. The manufacturing at the Maryland-based facility have been transferred to a third-party manufacturer and the sales and distribution of the products at this facility have been transferred to our newly-formed shared service center in Orlando, Florida. We recorded \$1.0 million in exit costs, including \$0.8 million related to facility and other exit costs and \$0.2 million related to severance costs. As of September 30, 2008, \$0.8 million in exit costs remain unpaid.

In connection with our acquisition of Matria, we implemented an integration plan to improve operating efficiencies and eliminate redundant costs resulting from the acquisition. The restructuring plan impacted all cost centers within the Matria organization, as activities were combined with our existing business operations. We recorded \$14.8 million in exit costs, all of which relates to change in control and severance costs to involuntarily terminate employees. As of September 30, 2008, \$7.6 million in severance costs remain unpaid.

See Note 9 for additional restructuring charges related to the Cholestech, HemoSense and Panbio facility closures and integration.

*(d) Pro Forma Financial Information*

The following table presents selected unaudited financial information of our company, including the assets of Instant, Biosite, Cholestech and Matria, as if the acquisitions of these entities had occurred on January 1, 2007. Pro forma results also reflect the impact of the formation of our consumer diagnostic business joint venture with P&G (Note 10(a)(i)) as if the joint venture had been formed on January 1, 2007. Pro forma results exclude adjustments for

**Table of Contents**

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

various other less significant acquisitions completed since January 1, 2007, 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, 2007 (in thousands, except per share amount).

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Pro forma net revenue	\$ 438,800	\$ 339,033	\$ 1,324,535	\$ 985,749
Pro forma net loss	\$ (5,791)	\$ (20,346)	\$ (58,337)	\$ (105,691)
Pro forma net loss per common share basic and diluted (1)	\$ (0.07)	\$ (0.38)	\$ (0.75)	\$ (1.99)

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

**(9) Restructuring Plans***(a) 2008 Restructuring Plans*

In May 2008, we decided to close our facility located in Bedford, England, and initiated steps to cease operations at this facility and transition the manufacturing operations principally to our manufacturing facilities in Shanghai and Hangzhou, China. Based upon this decision, we recorded \$1.9 million in restructuring charges during the three months ended September 30, 2008, including \$1.3 million of fixed asset impairments, \$0.5 million in severance and retention costs and \$0.1 million related to the acceleration of facility restoration costs. During the nine months ended September 30, 2008, we recorded \$12.7 million in restructuring charges, including \$6.7 million related to the acceleration of facility restoration costs, \$4.6 million of fixed asset impairments, \$0.7 million in early termination lease penalties and \$0.7 million in severance costs. Of these restructuring charges, \$6.0 million was charged to our professional diagnostic products business segment as follows: \$3.5 million to cost of net product sales, \$0.1 million to research and development expense, \$0.2 million to sales and marketing expense and \$2.2 million to general and administrative expense. We also recorded \$6.7 million related to the accelerated present value accretion of our lease restoration costs due to the early termination of our facility lease to interest expense. Of the exit costs under this plan, including severance, lease penalties and restoration costs, \$7.7 million remains unpaid as of September 30, 2008.

In addition to the restructuring charges discussed above, \$11.2 million of charges associated with the Bedford facility closure were borne by SPD Swiss Precision Diagnostics, or SPD, our consumer diagnostic joint venture with The Procter and Gamble Company, or P&G, during the nine month ended September 30, 2008. Included in these charges were \$6.0 million of fixed asset impairments, \$3.6 million in early termination lease penalties, \$1.5 million in severance and retention costs and \$0.1 million related to the acceleration of facility restoration costs. Of these restructuring charges, 50%, or \$5.6 million, has been included in equity earnings of unconsolidated entities, net of tax, on our consolidated statements of operations for the nine months ended September 30, 2008. We anticipate incurring additional costs of approximately \$28.0 million related to the closure of this facility, including, but not limited to,

severance and retention costs, rent obligations and incremental interest expense associated with our lease obligations which will terminate the end of 2011. Of these additional anticipated costs, approximately \$20.5 million will be borne by SPD and \$7.5 million will be borne by us. We expect the majority of these costs to be incurred by the end of 2009, which is our anticipated facility closure date.

In April 2008, we initiated cost reduction efforts at our facilities in Stirling, Scotland, consolidating our business activities into one facility and with our Biosite operations. As a result of these efforts, we recorded \$0.1 million and \$3.2 million in restructuring charges for the three and nine months ended September 30, 2008, respectively, consisting of \$2.0 million in fixed asset impairments, \$1.0 million in severance costs and \$0.2 million in facility exit costs. These charges are included in our professional diagnostic products business segment as follows: \$3.1 million to research and development expense and \$0.1 million to general and administrative expense. Of the \$1.2 million in

**Table of Contents**

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

severance and facility exit costs, \$0.1 million remains unpaid at September 30, 2008. We expect to record an additional \$0.1 million in costs primarily related to facility exit costs during the remainder of 2008.

In February 2008, we decided to cease research and development activities for one of the products in development at our Bedford, England facility, based upon comparison of the product under development with existing products acquired in the HemoSense acquisition. In connection with this decision, we recorded \$0.2 million as a reduction to restructuring charges associated with contractual obligations with suppliers through cost of net product sales during the three months ended September 30, 2008. During the nine months ended September 30, 2008, we recorded restructuring charges of \$9.5 million, of which \$6.8 million related to the impairment of fixed assets, \$1.9 million related to the write-off of inventory, \$0.6 million related to contractual obligations with suppliers and \$0.2 million related to severance costs to involuntarily terminate employees working on the development of this product. The \$9.5 million was included in our professional diagnostic products business segment and included \$6.1 million charged to cost of net product sales, \$3.3 million charged to research and development expense and \$0.1 million charged to sales and marketing expense. Of the \$0.7 million in contractual obligations and severance costs, \$0.5 million remains unpaid as of September 30, 2008. We do not expect to incur significant additional charges under this plan.

On March 18, 2008, we announced our plans to close our BioStar, Inc., or BioStar, facility in Louisville, Colorado, and exit production of the BioStar OIA product line, along with our plans to close two of our newly-acquired facilities in the San Francisco, California area, relating to Cholestech and HemoSense. The Cholestech operation, which was acquired in September 2007 and manufactures and distributes the Cholestech LDX system, a point-of-care monitor of blood cholesterol and related lipids used to test patients at risk of, or suffering from, heart disease and related conditions, will move to our Biosite facility in San Diego, California. The HemoSense operation, which was acquired in November 2007 and manufactures and distributes the INRatio System, an easy-to-use, hand-held blood coagulation monitoring system for use by patients and healthcare professionals in the management of warfarin, a commonly prescribed medication used to prevent blood clots, is also expected to move to the Biosite facility. The transfers will take place in phases with the HemoSense transition expected to be completed by December 31, 2008 and the Cholestech transition by the middle of 2009.

BioStar manufacturing ceased at the end of June 2008, with BioStar OIA products available for purchase through the end of the first quarter of 2009. During the three months ended September 30, 2008, we incurred \$1.6 million in restructuring charges related to this plan, which consisted of \$1.1 million in facility exit costs, \$0.3 million in severance related costs and \$0.2 million related to the write-off of inventory. Of the \$1.6 million, \$0.4 million was charged to cost of net product sales and \$1.2 million was charged to general and administrative expense. During the nine months ended September 30, 2008, we incurred \$9.5 million in restructuring charges related to this plan, which consisted of \$5.1 million in impairment of intangible assets, \$1.4 million in severance related costs, \$0.7 million in fixed asset impairments, \$1.1 million in facility exit costs and \$1.2 million related to the write-off of inventory. Of the \$9.5 million, which is included in our professional diagnostic products business segment, \$6.1 million was charged to cost of net product sales, \$1.9 million was charged to sales and marketing expense and \$1.5 million was charged to general and administrative. We expect to incur an additional \$0.1 million in charges under this plan during the remainder of 2008, primarily related to severance and facility exit costs. As of September 30, 2008, \$0.9 million in severance and facility exit costs remain unpaid.

As a result of our plans to transition the businesses of Cholestech and HemoSense to Biosite and close these facilities, we incurred \$1.2 million in restructuring charges during the three months ended September 30, 2008, related to \$0.6 million in severance and retention costs, \$0.3 million in fixed asset impairments, \$0.1 million in transition costs and \$0.2 million in present value accretion of facility lease costs. During the nine months ended September 30, 2008, we recorded \$1.9 million in restructuring charges, of which \$1.2 million relates to severance and retention costs, \$0.3 million in fixed asset impairments, \$0.2 million in transition costs and \$0.2 million in present value accretion of facility lease costs related to these plans. Of the \$1.7 million included in our professional diagnostic products business segment, \$0.6 million was charged to cost of net product sales, \$0.3 million was charged to research and development

expense, \$0.1 million was charged to sales and marketing expense and \$0.7 million was charged to general and administrative expense. We also recorded \$0.2 million related to the present

**Table of Contents**

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

value accretion of our facility lease costs due to the early termination of our facility lease to interest expense. Of the \$1.6 million in exit costs, \$1.4 million remains unpaid as of September 30, 2008.

In connection with our January 2008 acquisition of Panbio, we recorded \$0.1 million and \$0.3 million of restructuring charges during the three and nine months ended September 30, 2008, respectively, associated with our decision to close Panbio's Columbia, Maryland facility by the end of 2008. These charges are included in our professional diagnostic products business segment and \$0.1 million remains unpaid as of September 30, 2008.

We anticipate incurring an additional \$2.1 million in restructuring charges under our Cholestech, HemoSense and Panbio plans, primarily related to severance, retention and outplacement benefits, along with other costs to transition the Cholestech and HemoSense operations to our Biosite and third-party facilities. See Note 8(c) for further information and costs related to these plans.

In addition to transitioning the businesses of Cholestech and HemoSense to Biosite, we also made the decision to close our Innovacon facility in San Diego, California and move the operating activities to Biosite; the Innovacon business is the rapid diagnostics business that we acquired from ACON Laboratories, Inc. During the three and nine months ended September 30, 2008, we recorded \$0.6 million in restructuring charges, of which \$0.5 million relates to facility lease and exit costs and \$0.1 million relates to impairment of fixed assets. These charges are included in our professional diagnostic products business segment and were charged to general and administrative costs. As of September 30, 2008, substantially all restructuring costs remain unpaid. We vacated the facility in August 2008 and do not anticipate incurring additional costs under this plan.

*(b) 2007 Restructuring Plans*

During 2007, we committed to several plans to restructure and integrate our world-wide sales, marketing, order management and fulfillment operations, as well as evaluate certain research and development projects. The objectives of the plans are to eliminate redundant costs, improve customer responsiveness and improve efficiencies in operations. As a result of these restructuring plans, we recorded \$0.6 million in restructuring charges during the three months ended September 30, 2008. The \$0.6 million charge related primarily to severance costs in our professional diagnostic products business segment and consisted of \$0.4 million charged to sales and marketing expense and \$0.2 million charged to general and administrative expense. For the nine months ended September 30, 2008, we recorded \$1.9 million in net restructuring charges under these plans, which primarily relates to charges for severance and outplacement services. The \$1.9 million charge relates primarily to our professional diagnostic products business segment and consisted of \$0.1 million charged to cost of net product sales, \$1.1 million charged to sales and marketing expense and \$0.7 million charged to general and administrative expense. As of September 30, 2008, \$0.5 million of severance-related charges remain unpaid. Restructuring charges since the commitment date consist of \$3.1 million related to severance costs and \$4.0 million related to impairment charges on fixed assets. Of the \$7.1 million restructuring charges recorded in operating income, \$5.3 million and \$1.8 million were included in our professional diagnostic products and consumer diagnostic products business segments, respectively. We anticipate incurring \$0.3 million in additional severance charges related to this plan over the remainder of 2008.

In addition, we recorded restructuring charges associated with the formation of our joint venture with P&G. 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 nine months ended September 30, 2008, we recorded \$0.1 million in severance costs related to this plan, which was primarily charged to general and administrative expense. Since formation of the joint venture in May 2007, we have incurred \$1.3 million in severance and exit costs, of which \$0.1 million remains unpaid as of September 30, 2008.

**Table of Contents**

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

**(10) Investment in Unconsolidated Entities and Marketable Securities**

*(a) Equity Method Investments*

**(i) Joint Venture with P&G**

In May 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 \$63.6 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.

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. The deferred gain recorded on our accompanying consolidated balance sheets as of September 30, 2008 and December 31, 2007 was \$291.1 million and \$293.1 million, respectively.

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 \$26.6 million and \$79.0 million, and \$25.8 million and \$40.1 million in manufacturing revenue for the three and nine months ended September 30, 2008 and 2007, respectively, which are included in net product sales on our accompanying consolidated statements 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 \$0.5 million and \$1.9 million, and \$1.1 million and \$1.7 million, for the three and nine months ended September 30, 2008 and 2007, respectively, and are included in services revenue on our consolidated statements of operations. Customer receivables associated with this revenue have been classified as other receivables within prepaid and other current assets on our accompanying consolidated balance sheets in the amount of \$18.2 million and \$29.5 million as of September 30, 2008 and December 31, 2007, respectively. In connection with the joint venture arrangement, the joint venture bears the collection risk associated with these receivables.

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 Accounting Principles Board (APB) Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*. For the three and nine months ended September 30, 2008, we recorded earnings of \$2.8 million and a loss of \$0.2 million, respectively, in equity earnings (losses) of unconsolidated entities, net of tax, on our accompanying consolidated statements of operations, which represented our 50% share of the joint venture's net income (loss) for the respective periods including \$5.6 million of restructuring related charges (see Note 9(a)). For the three and nine months ended September 30, 2007, we recorded \$0.7 million and \$1.7 million, respectively, in equity earnings of unconsolidated entities, net of tax, on our accompanying consolidated statements of operations, which represented our 50% share of the joint venture's net income for the respective periods.

**(ii) TechLab**

In May 2006, we acquired 49% of TechLab, Inc., or 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 approximately 0.3 million shares of our common stock with an aggregate fair value of \$8.6 million and \$0.2 million in estimated direct acquisition costs. We account for our 49% investment in TechLab under the equity method of accounting, in



accordance with APB Opinion No. 18. In March 2008, June 2008 and September 2008, we received \$0.4 million, \$0.5 million and \$0.5 million, respectively, from TechLab in the form of a dividend distribution. These distributions were accounted for as reductions in the value of our investment in accordance with APB Opinion No.

**Table of Contents**

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

18. For the three and nine months ended September 30, 2008, we recorded earnings of \$0.3 million and \$1.2 million, respectively, in equity earnings (losses) of unconsolidated entities, net of tax, in our accompanying consolidated statements of operations. 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 statements of operations, which represented our minority share of TechLab's net income for the respective period.

(iii) Vedalab

We account for our 40% investment in Vedalab S.A., or Vedalab, a French manufacturer and supplier of rapid diagnostic tests in the professional market, under the equity method of accounting in accordance with APB Opinion No. 18. For the three and nine months ended September 30, 2008, we recorded \$0.1 million and \$0.2 million, respectively, in equity earnings of unconsolidated entities, net of tax, in our accompanying consolidated statements of operations. For the three and nine months ended September 30, 2007, we recorded earnings of \$0.2 million and \$0.2 million, respectively, in equity earnings of unconsolidated entities, net of tax, in our accompanying consolidated statements of operations, which represented our minority share of Vedalab's net income for the respective period.

(b) *Investment in Chembio*

At September 30, 2008, we owned approximately 5.4 million shares of common stock in Chembio Diagnostics, Inc., or Chembio, a developer and manufacturer of rapid diagnostic tests for infectious diseases. As of September 30, 2008 and December 31, 2007, the fair market value of our investment in Chembio was approximately \$0.8 million and \$1.4 million, respectively. This investment was classified as marketable securities, non-current on our accompanying consolidated balance sheets. We recorded an associated unrealized holding loss of approximately \$1.2 million and \$0.6 million in accumulated other comprehensive income within stockholders' equity in our accompanying consolidated balance sheets as of September 30, 2008 and December 31, 2007, respectively.

(c) *Investment in BBI*

At December 31, 2007, the fair market value of our investment in BBI, which was included in marketable securities, non-current on our accompanying consolidated balance sheets, was approximately \$19.0 million. The associated unrealized holding gain of approximately \$4.3 million was recorded in accumulated other comprehensive income within stockholders' equity in our accompanying consolidated balance sheets as of December 31, 2007. We acquired BBI in February 2008, at which time we recorded the original cost of this investment as part of our preliminary aggregate purchase price and reversed the \$4.3 million unrealized holding gain from accumulated other comprehensive income.

(d) *Investment in StatSure*

In October 2007, we acquired 5% of StatSure Diagnostic Systems, Inc., or StatSure, a developer and marketer of oral fluid collection devices for the drugs of abuse market, through the purchase of 1.4 million shares of their common stock. The aggregate purchase price of \$0.5 million was paid in cash. In addition to the common stock, we received a warrant to purchase 1.1 million shares of StatSure's common stock at \$0.35 per share. StatSure'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 \$0.3 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 assuming no dividend yield, an expected volatility of 150%, a risk-free rate of 3.9% and a contractual term of five years. We mark to market the warrant over the contractual term and recorded an unrealized loss of \$0.2 million in other income (expense), net on our accompanying consolidated statements of operations for the nine months ended September 30, 2008. As of September 30, 2008, the warrant was valued at \$0.1 million.

**Table of Contents**

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

**(11) Long-term Debt**

We had the following long-term debt balances outstanding (in thousands):

	<b>September 30, 2008</b>	<b>December 31, 2007</b>
First Lien Credit Agreement Term loan	\$ 963,188	\$ 970,500
First Lien Credit Agreement Revolving line-of-credit	142,000	
Second Lien Credit Agreement	250,000	250,000
3% Senior subordinated convertible notes	150,000	150,000
Lines-of-credit	3,482	3,730
Other	15,477	12,485
	1,524,147	1,386,715
Less: Current portion	(19,427)	(20,320)
	\$ 1,504,720	\$ 1,366,395

At September 30, 2008, we had a term loan in the amount of \$963.2 million and a revolving line-of-credit available to us of up to \$150.0 million, of which \$142.0 million was outstanding as of September 30, 2008, 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 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. The Base Rate is a floating rate which approximates the U.S. Prime rate and changes on a periodic basis. The Eurodollar Rate is equal to the LIBOR rate and is set for a period of one to three months at our election. 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, 2008, 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%.

At September 30, 2008, we had \$150.0 million in indebtedness under our 3% senior subordinated convertible notes, or senior subordinated convertible notes. The senior subordinated convertible notes are convertible into 3.4 million shares of our common stock at a conversion price of \$43.98.

We evaluated the agreement for the senior subordinated convertible notes 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. Accordingly, no fair value has been recorded for these items.

For the three and nine months ended September 30, 2008, interest expense, including amortization of deferred financing costs, under the secured credit facilities was \$21.3 million and \$64.9 million, respectively. For the three and nine months ended September 30, 2007, we recorded interest expense, including amortization of deferred financing costs, under our previous senior credit facility in the aggregate amount of \$27.5 million and \$33.8 million, respectively. Included in interest expense for the three and nine months ended September 30, 2007, is the write-off of \$0 and \$2.6 million, respectively, in unamortized deferred financing costs. As of September 30, 2008, accrued interest related to the secured credit facilities amounted to \$1.7 million. As of September 30, 2008, we were in compliance with all debt covenants related to the above debt, which consisted principally of maximum consolidated leverage and minimum interest coverage requirements.

**Table of Contents**

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

Interest expense related to our senior subordinated convertible notes for the three and nine months ended September 30, 2008, including amortization of deferred financing costs, was \$1.2 million and \$3.7 million, respectively. As of September 30, 2008, accrued interest related to the senior subordinated convertible notes amounted to \$1.7 million.

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 pay us variable interest at the three-month LIBOR rate, and we pay the counterparties a fixed rate of 4.85%. These interest rate swap contracts were entered into to convert \$350.0 million of the \$1.2 billion variable rate term loan under the secured credit facility into fixed rate debt.

**(12) Derivative Financial Instruments**

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

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. 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 until earnings are affected by the variability of cash flows. As of September 30, 2008 and December 31, 2007, we recorded losses of \$9.9 million and \$9.5 million, respectively, in accumulated other comprehensive income on the accompanying consolidated balance sheets (see Note 11).

See Note 10(d) regarding our StatSure warrants which are accounted for as derivative instruments.

**(13) Fair Value Measurements**

Effective January 1, 2008, we implemented SFAS No. 157, *Fair Value Measurement*, for our financial assets and liabilities that are re-measured and reported at fair value at each reporting period-end date, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. In accordance with the provisions of Financial Accounting Standards Board ( FASB ) Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, we have elected to defer implementation of SFAS No. 157 as it relates to our non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until January 1, 2009. We are evaluating the impact, if any, this Standard will have on our non-financial assets and liabilities. The adoption of SFAS No. 157 to our financial assets and liabilities and non-financial assets and liabilities that are re-measured and reported at fair value at least annually did not have an impact on our financial results.

Financial assets and liabilities recorded on the accompanying condensed consolidated balance sheets are categorized based on the inputs to the valuation techniques as follows:

*Level 1* - Financial assets and liabilities whose values are based on unadjusted quoted prices for identical assets or liabilities in an active market that the company has the ability to access at the measurement date (examples include active exchange-traded equity securities, listed derivatives and most U.S. Government and agency securities).

*Level 2* - Financial assets and liabilities whose values are based on quoted prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets. Level 2 inputs include the following:

**Table of Contents**

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

Quoted prices for identical or similar assets or liabilities in non-active markets (examples include corporate and municipal bonds which trade infrequently);

Inputs other than quoted prices that are observable for substantially the full term of the asset or liability (examples include interest rate and currency swaps); and

Inputs that are derived principally from or corroborated by observable market data for substantially the full term of the asset or liability (examples include certain securities and derivatives).

*Level 3* - Financial assets and liabilities whose values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs reflect management's own assumptions about the assumptions a market participant would use in pricing the asset or liability. We currently do not have any Level 3 financial assets or liabilities.

The following table presents information about our assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2008, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value (in thousands):

Description	September 30, 2008	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Marketable securities	\$ 2,799	\$ 2,799	\$
Strategic investments (1)	229	229	
Total assets	\$ 3,028	\$ 3,028	\$
Liabilities:			
Interest rate swap liability (2)	\$ 9,874	\$	\$ 9,874
Total liabilities	\$ 9,874	\$	\$ 9,874

(1) Represents our investment in StatSure which is included in investments in unconsolidated entities on our accompanying consolidated balance sheets.

(2) Included in other long-term

liabilities in our  
accompanying  
consolidated  
balances sheets.

**(14) Defined Benefit Pension Plan**

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Service cost	\$	\$	\$	\$
Interest cost	185	155	571	458
Expected return on plan assets	(161)	(129)	(497)	(381)
Realized losses		89		262
Net periodic benefit cost	\$ 24	\$ 115	\$ 74	\$ 339

**(15) Financial Information by Segment**

Under SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. Our chief operating decision-making group is composed of the chief executive officer and members of senior management. Our reportable operating segments are Professional Diagnostic Products, Health Management, Consumer Diagnostic Products, Vitamins and Nutritional Supplements and Corporate and Other. Our operating results include license and royalty revenue which is allocated to

**Table of Contents**

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

Professional Diagnostic Products and Consumer Diagnostic Products on the basis of the original license or royalty agreement.

Included in the operating results of Professional Diagnostic Products for the three and nine months ended September 30, 2008 are expenses related to our research and development activities related to new platform development in the area of cardiology which amounted to \$7.5 million and \$32.2 million, respectively.

Included in the operating results of Corporate and Other for the three and nine months ended September 30, 2007 are expenses related to our research and development activities in the area of cardiology, which amounted to \$8.6 million, net of \$4.8 million of reimbursements received from ITI Scotland Limited, or ITI, and \$18.4 million, net of \$13.7 million of reimbursements received from ITI, respectively, as part of the co-development arrangement that we entered into in February 2005 and culminated as of December 31, 2007.

Total assets related to our cardiology research operations in Scotland and Germany, which are included in Professional Diagnostic Products as of September 30, 2008 and December 31, 2007 in the tables below amounted to \$36.2 million and \$39.4 million, respectively. Assets related to our newly-formed health management business segment, in the amount of \$635.4 million, have been reclassified from Professional Diagnostic Products to Health Management as of December 31, 2007. Results of operations related to our newly-formed health management business segment have been reclassified from Professional Diagnostic Products to Health Management during the quarter in which they were incurred during 2007. Operating loss in the amount of \$0.3 million and operating income of \$48,000 for QAS have been reclassified from Professional Diagnostic Products to Health Management for the three and nine months ended September 30, 2007, respectively. Net revenue to external customers for QAS in the amount of \$5.3 million and \$6.7 million have been reclassified from Professional Diagnostic Products to Health Management for the three and nine months ended September 30, 2007, respectively. The remaining health management businesses, consisting of Alere, ParadigmHealth, Matria and our most recently acquired healthcare business, were acquired subsequent to September 30, 2007.

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, 2008 and 2007 is as follows (in thousands):

	Professional Diagnostic Products	Health Management	Consumer Diagnostic Products	Vitamins and Nutritional Supplements	Corporate and Other	Total
<b>Three months ended September 30, 2008:</b>						
Net revenue to external customers	\$ 256,769	\$ 124,092	\$ 36,313	\$ 21,626	\$	\$ 438,800
Operating income (loss)	\$ 22,807	\$ 549	\$ 3,042	\$ (71)	\$ (13,080)	\$ 13,247
<b>Three months ended September 30, 2007:</b>						
Net revenue to external customers	\$ 178,328	\$ 5,335	\$ 33,263	\$ 20,710	\$	\$ 237,636
Operating income (loss)	\$ 17,677	\$ (256)	\$ 3,600	\$ 607	\$ (178,103)	\$ (156,475)

**Nine months ended  
September 30, 2008:**



Net revenue to external customers	\$	780,079	\$	261,780	\$	108,234	\$	62,067	\$		\$	1,212,160
Operating income (loss)	\$	54,820	\$	7,832	\$	8,408	\$	513	\$	(40,046)	\$	31,527

**Nine months ended  
September 30, 2007:**

Net revenue to external customers	\$	360,089	\$	6,700	\$	131,148	\$	53,643	\$		\$	551,580
Operating income (loss)	\$	38,071	\$	48	\$	16,098	\$	(2,094)	\$	(234,804)	\$	(182,681)

**Assets:**

As of September 30, 2008	\$	3,693,147	\$	1,891,538	\$	243,425	\$	60,710	\$	54,358	\$	5,943,178
As of December 31, 2007	\$	3,748,931	\$	635,415	\$	309,175	\$	49,655	\$	137,583	\$	4,880,759

**(16) Related Party Transactions**

In May 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 September 30, 2008 and December 31, 2007, we had a net payable to the joint venture of \$0.2 million and \$10.8 million, respectively, representing our obligation to the joint venture. Additionally, customer receivables

**Table of Contents**

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

associated with revenue earned after the joint venture was completed have been classified as other receivables within prepaid and other current assets on our accompanying consolidated balance sheets in the amount of \$18.2 million and \$29.5 million as of September 30, 2008 and December 31, 2007, respectively. In connection with the joint venture arrangement, the joint venture bears the collection risk associated with these receivables. Sales to the joint venture under our manufacturing agreement totaled \$26.6 million and \$79.0 million during the three and nine months ended September 30, 2008, respectively, and are included in net product sales on our accompanying statements of operations. During 2008, the joint venture paid \$11.2 million in cash to both of the parent companies, equally reducing the respective investments in the joint venture.

**(17) Material Contingencies and Legal Settlements**

Due to the nature of our business, we may from time to time be subject to commercial disputes, consumer product claims or various other lawsuits, 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.

On September 19, 2008, the Estate of Melissa Prince Quisenberry filed a class action complaint in the Superior Court of California on behalf of herself and others similarly situated against Alere Medical Inc. ( Alere ) and Agora Parent, Inc., both our wholly owned subsidiaries; Ronald D. Geraty, MD, Chief Executive Officer of Alere and certain other individuals who were executive officers, directors and/or significant shareholders of Alere (collectively the Alere Individual Defendants ); as well as certain other unaffiliated entities alleging that the Alere Individual Defendants breached fiduciary duties of good faith, fair dealing, loyalty and candor; and that Alere and certain unaffiliated entities aided, abetted and substantially participated in the breach of fiduciary duty. Plaintiff and class owned common and/or preferred stock in Alere and allege that the defendants forced them to tender their stock in connection with the March 14, 2007 sale of Alere to an unaffiliated entity at a price which was substantially lower than the price at which we bought Alere on October 24, 2007.

Otherwise, we are not a party to any legal proceedings that we currently believe could materially adversely affect our results of operations or financial condition or net cash flows.

In June 2008, we received an unfavorable ruling from an arbitration panel resulting in a \$12.5 million settlement payable to one of our distributors located in Spain and Portugal. In addition to the \$12.5 million settlement, which was recorded in other income/(expense) in our accompanying consolidated statements of operations, we recorded \$0.7 million of interest expense during the nine months ended September 30, 2008. The settlement amount and related interest expense were paid during the three months ended September 30, 2008.

We have contingent consideration contractual terms related to our acquisitions of Alere, Binax, Inc., or Binax, Bio-Stat, CLONDIAG chip technologies GmbH, or Clondiag, Diamics, First Check, Gabmed, Matritech, Promesan, Spectral/Source, our most recently acquired healthcare business, Vision and Global. With the exception of Alere, the contingent considerations will be accounted for as increases in the aggregate purchase prices if and when the contingencies occur.

With respect to Alere, the terms of the acquisition agreement provided for contingent consideration payable to each Alere stockholder who owned shares of our common stock or retained the option to purchase shares of our common stock on the 6-month anniversary of the closing of the acquisition. The contingent consideration, payable in cash or stock at our election, was equal to the number of such shares of our common stock or options to purchase our common stock held on the 6-month anniversary multiplied by the amount that \$58.31 exceeded the greater of the average price of our common stock for the 10 business days preceding the 6-month anniversary date, or 75% of \$58.31. Accordingly, based on the price of our common stock for the 10 business days preceding the 6-month anniversary of the closing of the acquisition, we issued approximately 0.1 million shares of our common stock on May 30, 2008 to the Alere stockholders based on the remaining outstanding shares at that time. Payment of this contingent

consideration did not impact the purchase price for this acquisition.

27

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**Table of Contents**

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

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. As of September 30, 2008, the remaining contingent consideration to be earned is approximately \$7.3 million.

With respect to Bio-Stat, the terms of the acquisition provide for contingent consideration payable in the form of loan notes to the Bio-Stat shareholders, if certain EBITDA (earnings before interest, taxes, depreciation and amortization) milestones are met for 2007. The EBITDA milestones were met in 2007 and loan notes totaling \$6.2 million were issued during the third quarter of 2008 and remain outstanding as of September 30, 2008.

With respect to Clondia, the terms of the acquisition agreement provide for \$8.9 million of contingent consideration, consisting of approximately 0.2 million shares of our common stock and approximately \$3.0 million of cash or stock in the event that four specified products are developed on Clondia's platform technology during the three years following the acquisition date. Successful completion of the second milestone occurred during the first quarter of 2008 for which we made a payment for \$0.9 million and issued 56,080 shares of our common stock during the first quarter of 2008. Successful completion of the third and fourth milestones occurred during the third quarter of 2008 and, accordingly, contingent consideration of \$4.8 million was accrued as of September 30, 2008.

With respect to Diamics, the terms of the acquisition agreement provide for contingent consideration payable upon the successful completion of certain milestones, including development of business plans and marketable products. As of September 30, 2008, the remaining contingent consideration to be earned is approximately \$2.3 million.

With respect to First Check, the terms of the acquisition agreement require us to 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. The 2007 milestone, totaling \$2.2 million, was met and accrued as of December 31, 2007 and was paid during the first quarter of 2008. As of September 30, 2008, the second earn-out requirements were met resulting in accrued contingent consideration of \$0.3 million during the third quarter of 2008.

With respect to Gabmed, the terms of the acquisition agreement provide for contingent consideration totaling up to 750,000 payable in up to five annual amounts beginning in 2007, upon successfully meeting certain revenue and EBIT (earnings before interest and taxes) milestones in each of the respective annual periods. The 2007 milestone, totaling 0.1 million (\$0.2 million), was met and accrued as of June 30, 2008 and was paid during the third quarter of 2008.

With respect to Matritech, the terms of the acquisition agreement require us to pay an earn-out to the former Matritech shareholders upon successfully meeting certain revenue targets in 2008. As of September 30, 2008, no milestones have been met.

With respect to Promesan, the terms of the acquisition agreement provide for contingent consideration payable upon successfully meeting certain annual revenue targets. Total contingent consideration of up to 0.6 million is payable in three equal annual amounts of 0.2 million beginning in 2007 and ending in 2009. The 2007 milestone, totaling 0.2 million (\$0.3 million), was met and accrued as of December 31, 2007 and was paid during the first quarter of 2008.

With respect to Spectral/Source, the terms of the acquisition agreement require us to 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. As of September 30, 2008, revenue and profit milestones were achieved resulting in accrued contingent consideration of \$2.7 million.

**Table of Contents**

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

With respect to our most recently acquired healthcare business, the terms of the acquisition agreement provide for contingent consideration payable upon successfully meeting certain revenue and EBITDA targets for the twelve months ending June 30, 2009 and December 31, 2010, respectively. As of September 30, 2008, we accrued a liability in the amount of \$5.8 million to avoid recognition of negative goodwill, as a result of not recognizing additional purchase price consideration that is contingent on future events.

With respect to Vision, the terms of the acquisition agreement provide for incremental consideration payable to the former Vision shareholders. The maximum amount of incremental consideration payable is approximately \$3.2 million, of which \$1.0 million is guaranteed and accrued as of September 30, 2008. The remaining contingent consideration is payable upon the completion of certain milestones and successfully maintaining certain production levels and product costs during each of the two years following the acquisition date.

With respect to Global, the terms of the acquisition agreement provide for contingent consideration payable upon successfully meeting certain revenue targets in 2008. As of September 30, 2008, no milestones have been met.

**(18) Recent Accounting Pronouncements**

*Recently Issued Standards*

In October 2008, the FASB issued FASB Staff Position ( FSP ) 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*. FSP 157-3 clarifies the application of SFAS No. 157 in an inactive market. It demonstrated how the fair value of a financial asset is determined when the market for that financial asset is inactive. FSP 157-3 was effective upon issuance, including prior periods for which financial statements had not been issued. The adoption of these provisions did not have a material impact on our consolidated financial statements.

In June 2008, the FASB ratified EITF Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock*, which addresses the accounting for certain instruments as derivatives under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. Under this new pronouncement, specific guidance is provided regarding requirements for an entity to consider embedded features as indexed to the entity's own stock. This Issue is effective for fiscal years beginning after December 15, 2008. We are currently in the process of evaluating the impact of adopting this pronouncement.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. This statement identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the United States. This statement is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. We do not expect SFAS No. 162 to have a material impact on our consolidated financial statements.

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled In Cash upon Conversion (Including Partial Cash Settlement)*. FSP APB 14-1 specifies that issuers of such instruments should separately account for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. FSP APB 14-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. We are currently in the process of evaluating the impact of adopting this pronouncement.

In April 2008, the FASB issued FSP 142-3, *Determination of the Useful Life of Intangible Assets*. FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, as well as interim periods within those fiscal years. We are currently in the process of evaluating the impact of adopting this pronouncement.

**Table of Contents**

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

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an Amendment of FASB Statement No. 133*. This statement requires entities that utilize derivative instruments to provide qualitative disclosures about their objectives and strategies for using such instruments, as well as any details of credit-risk-related contingent features contained within derivatives. It also requires entities to disclose additional information about the amounts and location of derivatives located within the financial statements, how the provisions of SFAS No. 133 have been applied and the impact that hedges have on an entity's financial position, financial performance and cash flows. This statement is effective for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. We are currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB ratified the consensus reached by the EITF in EITF Issue No. 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*. The EITF concluded that a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. Revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, and other accounting literature. Payments to or from collaborators would be evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature. The nature and purpose of collaborative arrangements are to be disclosed along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF Issue No. 07-01 applies to the entire collaborative agreement. This Issue is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We are currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an Amendment of Accounting Research Bulletin (ARB) No. 51*. This statement amends ARB No. 51 to establish accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a non-controlling interest in a subsidiary is an ownership interest in the consolidated entity and should therefore be reported as equity in the consolidated financial statements. The statement also establishes standards for presentation and disclosure of the non-controlling results on the consolidated income statement. SFAS No. 160 is effective for fiscal years beginning on or after December 15, 2008. We are currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB issued SFAS No. 141-R, *Business Combinations*. This statement replaces SFAS No. 141, but retains the fundamental requirements in SFAS No. 141 that the acquisition method of accounting be used for all business combinations. This statement requires an acquirer to recognize and measure the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at their fair values as of the acquisition date. The statement requires acquisition costs and any restructuring costs associated with the business combination to be recognized separately from the fair value of the business combination. SFAS No. 141-R establishes requirements for recognizing and measuring goodwill acquired in the business combination or a gain from a bargain purchase as well as disclosure requirements designed to enable users to better interpret the results of the business combination. SFAS No. 141-R is effective for fiscal years beginning on or after December 15, 2008. Given our history of acquisition activity, we anticipate the adoption of SFAS No. 141-R to have a significant impact on our consolidated financial statements. Early adoption of this statement is not permitted.

*Recently Adopted Standards*

Effective January 1, 2008, we adopted 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. The effect of

**Table of Contents**

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

applying this EITF is prospective for new contracts entered into on or after the date of adoption. The adoption of this EITF did not have a material impact on our consolidated financial statements.

Effective January 1, 2008, we adopted 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. The adoption of these provisions did not have a material impact on our consolidated financial statements.

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, for financial assets and liabilities, as well as for any other assets and liabilities that are carried at fair value on a recurring basis in financial statements. The FASB has provided a one year deferral for the implementation for other non-financial assets and liabilities. Earlier application is encouraged. We adopted the required provisions of SFAS No. 157 on January 1, 2008. The adoption of these provisions did not have a material impact on our consolidated financial statements. For further information about the adoption of the required provisions of SFAS No. 157 see Note 13.



**Table of Contents**

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

**Financial Overview**

We enable individuals to take charge of improving their health and quality of life by developing new capabilities in near patient diagnosis, monitoring and health management. As a leading global manufacturer and supplier of rapid diagnostics, our diagnostic products and development efforts are focused in the areas of infectious disease, cardiology, oncology, drugs of abuse and women's health. With our 2007 acquisitions of Biosite Incorporated, or Biosite, Cholestech Corporation, or Cholestech, and HemoSense, Inc., or HemoSense, we established our company as a leading supplier of cardiology diagnostic products. Our acquisitions of Biosite, Instant Technologies, Inc., or Instant, and Redwood Toxicology Laboratories, Inc., or Redwood, during 2007 enhanced our position in drugs of abuse testing. Additionally, with our December 2007 acquisition of Matritech, Inc., or Matritech, we also established a presence in oncology, by acquiring the unique NMP-22® ELISA and rapid point-of-care tests for the screening and monitoring of bladder cancer in conjunction with standard diagnostic procedures. We expect to continue to expand in all of these product categories through focused research and development projects and further development of our distribution capabilities.

During 2007 and 2008, we entered the growing health management market with our acquisitions of ParadigmHealth, Inc., or ParadigmHealth, Alere Medical Inc., or Alere, and more recently, Matria Healthcare, Inc., or Matria. With the acquisition of Matria, we are now a leader in this field offering a broad range of services aimed at lowering costs for health plans, hospitals, employers and patients. Our health management services are focused in the areas of women's and children's health, cardiology and oncology. We are confident that our ability to offer near patient monitoring tools combined with value-added healthcare services will improve care and lower healthcare costs for both providers and patients. During the third quarter of 2008, we began efforts to consolidate the health management businesses under a single brand. Today, Matria, ParadigmHealth and Alere, each a leader in their respective areas, are united as one business under the name Alere. Also during the third quarter of 2008, we acquired an overseas health management business enabling us to establish a presence in the newly-developing international health management market.

Our research and development programs have two general focuses. We are developing new technology platforms that will facilitate our primary objective of enabling individuals to take charge of improving their health and quality of life by moving testing out of the hospital and central laboratory, and into the physician's office and ultimately the home. Additionally, through our strong pipeline of novel proteins or combinations of proteins that function as disease biomarkers, we are developing new tests targeted towards all of our areas of focus.

We continue to advance toward our goal of establishing a worldwide distribution network that will allow us to bring both our current and future diagnostic products to the global professional market. In addition, we continue to focus on improving our margins through consolidation of certain of our higher cost manufacturing operations into lower cost facilities, including our 300,000 square foot manufacturing facility located in Hangzhou, China, as well as our jointly-owned facility in Shanghai, and we are already seeing improved margins on some of our existing products that we have moved to these facilities. Our business integration activities remain on track and we are beginning to see positive results as we continue to aggressively integrate acquired operations in order to achieve further synergies within expected timelines. During the second half of 2007, we began implementation of a plan to consolidate sales processing and certain other back-office services from seven of our U.S. operations into a shared service center, located in Orlando, Florida. This shared service center commenced operations at the beginning of the second quarter of 2008.

Net revenue increased by \$201.2 million, or 85%, to \$438.8 million for the three months ended September 30, 2008 from \$237.6 million for the three months ended September 30, 2007. Revenue increased primarily as a result of our newly-formed health management segment which provided \$118.7 million of incremental revenue and primarily included the activities of our recent acquisitions of Quality Assured Services, Inc., or QAS, Alere, ParadigmHealth and Matria. Also contributing to the increase in net revenue during the third quarter of 2008 were our other recently acquired businesses, primarily within our professional diagnostic products segment which provided \$63.5 million of incremental revenue. Net revenue increased by \$660.6 million, or 120%, to \$1.2 billion for the nine months ended

September 30, 2008, from \$551.6 million for the nine months ended September 30, 2007.

**Table of Contents**

Revenue increased primarily as a result of our professional diagnostic related acquisitions which contributed \$364.3 million of the increase. Also contributing to the increase in net revenue during the nine months ended September 30, 2008 was our newly-formed health management segment which contributed \$251.6 million of incremental revenue and included the activities of our recent acquisitions of QAS, Alere, ParadigmHealth, Matria and our most recently acquired healthcare business.

For the three and nine months ended September 30, 2008, we generated a net loss of \$3.7 million and \$38.2 million, respectively, compared to a net loss of \$180.6 million and \$229.0 million, for the three and nine months ended September 30, 2007, respectively.

**Results of Operations**

**Net Product Sales, Total and by Business Segment.** Total net product sales increased by \$79.1 million, or 35%, to \$305.3 million for the three months ended September 30, 2008, from \$226.1 million for the three months ended September 30, 2007. Excluding the favorable impact of currency translation, net product sales for the three months ended September 30, 2008 increased by \$78.0 million, or 35%, compared to the three months ended September 30, 2007. Total net product sales increased by \$387.4 million, or 73%, to \$918.5 million for the nine months ended September 30, 2008, from \$531.1 million for the nine months ended September 30, 2007. Excluding the favorable impact of currency translation, net product sales for the nine months ended September 30, 2008 increased by \$378.3 million, or 71%, compared to the nine months ended September 30, 2007. Net product sales by business segment for the three and nine months ended September 30, 2008 and 2007 are as follows (in thousands):

	<b>Three Months Ended September 30,</b>				<b>Nine Months Ended September 30,</b>		
	<b>2008</b>	<b>2007</b>	<b>% Change</b>		<b>2008</b>	<b>2007</b>	<b>% Change</b>
Professional diagnostic products	\$ 245,142	\$ 172,193	42%	\$	740,570	\$ 347,781	113%
Health management	4,307	3,985	8%		13,541	4,981	172%
Consumer diagnostic products	34,191	29,240	17%		102,306	124,727	(18)%
Vitamins and nutritional supplements	21,626	20,710	4%		62,067	53,643	16%
Total net product sales	\$ 305,266	\$ 226,128	35%	\$	918,484	\$ 531,132	73%

**Professional Diagnostic Products**

Net product sales of our professional diagnostic products increased by \$72.9 million, or 42%, comparing the three months ended September 30, 2008 to the three months ended September 30, 2007. Excluding the favorable impact from currency translation, net product sales of our professional diagnostic products increased by \$71.2 million, or 41%, comparing the three months ended September 30, 2008 to the three months ended September 30, 2007. Of the currency adjusted increase, revenue increased primarily as a result of our acquisitions of: (i) Cholestech, in September 2007, which contributed additional product revenue of \$12.0 million in excess of those earned in the prior year's comparative quarter, (ii) HemoSense, in November 2007, which contributed product revenue of \$8.5 million, (iii) BBI Holdings Plc, or BBI, in February 2008, which contributed product revenue of \$8.5 million and (v) various less significant acquisitions, which contributed an aggregate of \$23.1 million of such increase. Organic growth, particularly from our professional infectious disease products, also contributed to the growth. The currency adjusted organic growth for our professional diagnostic net product sales, excluding the impact of acquisitions, was 11%.

Net product sales of our professional diagnostic products increased by \$392.8 million, or 113%, comparing the nine months ended September 30, 2008 to the nine months ended September 30, 2007. Excluding the impact from currency translation, net product sales of our professional diagnostic products increased by \$383.6 million, or 110%,

comparing the nine months ended September 30, 2008 to the nine months ended September 30, 2007. Of the currency adjusted increase, revenue increased primarily as a result of our acquisitions of: (i) Biosite, in June 2007, which contributed additional product revenue of \$161.7 million in excess of those earned in the prior year's comparative period, (ii) Cholestech, in September 2007, which contributed additional product revenue of \$49.4 million in excess of those earned in the prior year's comparative period, (iii) Bio-Stat Healthcare Group, or Bio-Stat, in October 2007, which contributed product revenue of \$21.6 million, (iv) HemoSense, in November 2007, which contributed product revenue of \$23.7 million, (v) Redwood, in December 2007, which contributed product revenue of \$18.4 million, (vi) BBI, in February 2008, which contributed product revenue of \$23.0 million and (vii) various less significant acquisitions, which contributed an aggregate of \$39.1 million of such increase. Organic growth,

**Table of Contents**

particularly from our professional infectious disease products, also contributed to the growth. The currency adjusted organic growth for our professional diagnostic net product sales excluding the impact of acquisitions was 13%.

*Health Management*

Net product sales from our health management business segment increased by \$0.3 million, or 8%, comparing the three months ended September 30, 2008 to the three months ended September 30, 2007. Net product sales from our health management business segment increased by \$8.6 million, or 172%, comparing the nine months ended September 30, 2008 to the nine months ended September 30, 2007. The increase in net product sales in each of the respective periods represents organic growth of sales related to our acquisition of QAS in June 2007.

*Consumer Diagnostic Products*

Net product sales of our consumer diagnostic products increased by \$5.0 million, or 17%, comparing the three months ended September 30, 2008 to the three months ended September 30, 2007. The increase in net product sales is primarily attributed to our acquisitions of: (i) Bio-Stat, in October 2007, which contributed product revenue of \$2.3 million and (ii) BBI, in February 2008, which contributed product revenue of \$1.7 million.

Net product sales of our consumer diagnostic products decreased by \$22.4 million, or 18%, comparing the nine months ended September 30, 2008 to the nine months ended September 30, 2007. The decrease in net product sales is primarily driven by the completion of our 50/50 joint venture with The Procter & Gamble Company, or P&G, in May 2007 in which we transferred substantially all of the assets of our consumer diagnostic products business, other than our manufacturing and core intellectual property assets. 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. Net product sales of our consumer diagnostic products for the nine months ended September 30, 2008 does, however, include \$79.0 million of manufacturing revenue associated with our manufacturing agreement with the joint venture, whereby we manufacture and sell consumer diagnostic products to the joint venture. Partially offsetting the impact of the joint venture was an increase in revenue associated with the acquisitions of: (i) First Check Diagnostics LLC, or First Check, in January 2007, which contributed additional product revenue of \$1.1 million, (ii) Bio-Stat, in October 2007, which contributed product revenue of \$6.9 million and (iii) BBI, in February 2008, which contributed product revenue of \$4.4 million.

*Vitamins and Nutritional Supplements*

Our vitamins and nutritional supplements net product sales increased by \$0.9 million, or 4%, comparing the three months ended September 30, 2008 to the three months ended September 30, 2007, and increased by \$8.4 million, or 16%, comparing the nine months ended September 30, 2008 to the nine months ended September 30, 2007. The increase in each of the respective periods is primarily a result of organic growth from our existing customers.

**Services Revenue, Total and by Business Segment.** Services revenue is primarily related to our newly-formed health management business segment which primarily includes our recent acquisitions of QAS, Alere, ParadigmHealth and Matria. In addition to the services revenue generated by our health management businesses, services revenue also includes revenue generated by our professional drugs of abuse testing and screening business, along with revenue associated with our long-term services agreement related to our consumer diagnostic joint venture formed with P&G in May 2007, pursuant to which we provide certain operational support services to the joint venture. Our services revenue was \$127.8 million and \$272.2 million for the three and nine months ended September 30, 2008, respectively.

	<b>Three Months Ended September 30, 2008</b>		<b>Nine Months Ended September 30, 2008</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Professional diagnostic products	\$ 7,442	\$	\$ 22,032	\$
Health management	119,785	1,350	248,239	1,719
Consumer diagnostic products	541	1,090	1,929	1,670

Total services revenue	\$ 127,768	\$ 2,440	\$ 272,200	\$ 3,389
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34

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## **Table of Contents**

### *Professional Diagnostic Products*

Services revenue provided by our professional diagnostic business segment of \$7.4 million and \$22.0 million for the three and nine months ended September 30, 2008, respectively, represent revenue related to the laboratory-based professional drugs of abuse testing and screening business at Redwood, which was acquired in December 2007.

### *Health Management*

Services revenue provided by our newly-formed health management business segment was \$119.8 million and \$248.2 million for the three and nine months ended September 30, 2008, respectively, with Matria contributing services revenue of \$75.2 million and \$119.7 million in each of the respective periods, Alere contributing services revenue during the respective periods of \$22.9 million and \$68.2 million, ParadigmHealth contributing services revenue during the respective periods of \$18.2 million and \$52.7 million, and QAS contributing services revenue during the respective periods of \$3.0 million and \$7.1 million.

### *Consumer Diagnostic Products*

Services revenue provided by our consumer diagnostic business segment decreased by \$0.5 million, or 50%, comparing the three months ended September 30, 2008 to the three months ended September 30, 2007. Services revenue provided by our consumer diagnostic business segment increased by \$0.3 million, or 16%, comparing the nine months ended September 30, 2008 to the nine months ended September 30, 2007. Services revenue provided by our consumer diagnostic business segment represents revenue related to our long-term services agreements with our 50/50 joint venture with P&G formed in May 2007, pursuant to which we provide certain operational support services to the joint venture.

**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 decreased by approximately \$3.3 million, or 36%, to \$5.8 million for the three months ended September 30, 2008, from \$9.1 million for the three months ended September 30, 2007, and increased by approximately \$4.4 million, or 26%, to \$21.5 million for the nine months ended September 30, 2008, from \$17.1 million for the nine months ended September 30, 2007. The decrease in license and royalty revenue for the three months ended September 30, 2008 primarily relates to a \$2.6 million royalty/license fee received by Biosite during the third quarter of 2007. License and royalty revenue for the nine months ended September 30, 2008 increased primarily as a result of our acquisition of Biosite in June 2007, which contributed \$5.5 million of such increase. This increase was partially offset by decreases in existing royalty agreements.

**Gross Profit and Margin.** Gross profit increased by \$117.9 million, or 107%, to \$228.1 million for the three months ended September 30, 2008, from \$110.3 million for the three months ended September 30, 2007. Gross profit during the three months ended September 30, 2008 benefited primarily from higher than average margins earned on revenue from our recently acquired businesses, as discussed above. Gross profit for the three months ended September 30, 2008 included a \$1.9 million restructuring charge related to the closure of various manufacturing and operating facilities. Gross profit for the three months ended September 30, 2007 included 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.

Gross profit increased by \$359.7 million, or 141%, to \$614.6 million for the nine months ended September 30, 2008, from \$255.0 million for the nine months ended September 30, 2007. Gross profit during the nine months ended September 30, 2008 benefited primarily from higher than average margins earned on revenue from our recently acquired businesses, as discussed above. Gross profit for the nine months ended September 30, 2008 included a \$16.4 million restructuring charge related to the closure of various manufacturing and operating facilities and a \$2.0 million charge related to the write up to fair market value of inventory acquired in connection with our first quarter of 2008 acquisitions of BBI and Panbio Limited, or Panbio. Gross profit for the nine months ended September 30, 2007 included a \$7.5 million charge related to the write up to fair market value of inventory acquired in connection with our acquisitions of Biosite and Cholestech.

Cost of sales included amortization expense of \$10.5 million and \$7.5 million for the three months ended September 30, 2008 and September 30, 2007, respectively, and \$34.2 million and \$13.8 million for the nine months ended September 30, 2008 and September 30, 2007, respectively.





**Table of Contents**

Overall gross margin was 52% and 51% for the three and nine months ended September 30, 2008, respectively, compared to 46% for both the three and nine months ended September 30, 2007.

**Gross Profit from Net Product Sales, Total and by Business Segment.** Gross profit from net product sales represents net product sales less cost of net product sales. Gross profit from total net product sales increased by \$51.1 million, or 51%, to \$152.2 million for the three months ended September 30, 2008 from \$101.1 million for the three months ended September 30, 2007.

Gross profit from total net product sales increased by \$206.1 million, or 85%, to \$448.3 million for the nine months ended September 30, 2008 from \$242.2 million for the nine months ended September 30, 2007. Gross profit from net product sales by business segment for the three and nine months ended September 30, 2008 and 2007 are as follows (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2007	% Change	2008	2007	% Change
Professional diagnostic products	\$ 143,227	\$ 93,790	53%	\$ 419,393	\$ 186,792	125%
Health management	395	1,134	(65)%	3,006	1,539	95%
Consumer diagnostic products	6,703	3,528	90%	18,925	49,970	(62)%
Vitamins and nutritional supplements	1,838	2,605	(29)%	7,000	3,900	79%
Total gross profit from net product sales	\$ 152,163	\$ 101,057	51%	\$ 448,324	\$ 242,201	85%

*Professional Diagnostic Products*

Gross profit from net product sales for our professional diagnostic segment increased by \$49.4 million, or 53%, to \$143.2 million during the three months ended September 30, 2008, compared to \$93.8 million for the three months ended September 30, 2007. The increase in gross profit was largely attributed to the increase in net product sales resulting primarily from our acquisitions of Cholestech, HemoSense and BBI, as discussed above.

Gross profit from net product sales for our professional diagnostic segment increased by \$232.6 million, or 125%, to \$419.4 million during the nine months ended September 30, 2008, compared to \$186.8 million for the nine months ended September 30, 2007. The increase in gross profit was largely attributed to the increase in net product sales resulting primarily from our acquisitions of Biosite, Cholestech and HemoSense, as discussed above.

As a percentage of our professional diagnostic net product sales, gross margin for the three and nine months ended September 30, 2008 was 58% and 57%, respectively, compared to 54% for the three and nine months ended September 30, 2007.

*Health Management*

Gross profit from net product sales for our health management business segment decreased by \$0.7 million, or 65%, to \$0.4 million during the three months ended September 30, 2008, compared to \$1.1 million for the three months ended September 30, 2007.

Gross profit from net product sales for our health management business segment increased by \$1.5 million, or 95%, to \$3.0 million during the nine months ended September 30, 2008, compared to \$1.5 million for the nine months ended September 30, 2007. The increase in gross profit for the nine months ended September 30, 2008 primarily relates to our acquisition of QAS in June 2007.

As a percentage of our health management net product sales, gross margin for the three and nine months ended September 30, 2008 was 9% and 22%, respectively, compared to 28% and 31% for both the three and nine months ended September 30, 2007, respectively.

*Consumer Diagnostic Products*

Gross profit from net product sales for our consumer diagnostic segment increased by \$3.2 million, or 90%, to \$6.7 million for the three months ended September 30, 2008, compared to \$3.5 million for the three months ended

36

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**Table of Contents**

September 30, 2007. The increase during the three months ended September 30, 2008 is primarily a result of the gross profit earned on revenue from our acquisitions of BBI and Bio-Stat.

Gross profit from net product sales for our consumer diagnostic segment decreased by \$31.0 million, or 62%, to \$18.9 million for the nine months ended September 30, 2008, compared to \$50.0 million for the nine months ended September 30, 2007. The decrease during the nine months ended September 30, 2008 is primarily a result of the formation of our consumer diagnostic business joint venture with P&G in May 2007, partially offset by the gross profit earned on revenue from our acquisitions of BBI, Bio-Stat and First Check, as discussed above, and manufacturing profit associated with products sold under our manufacturing agreement with the joint venture.

As a percentage of our consumer diagnostic net product sales, gross margin for the three and nine months ended September 30, 2008 was 20% and 18%, respectively, compared to 12% and 40% for the three and nine months ended September 30, 2007, respectively. The increase in gross margin percentage for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007 is primarily a result of the gross profit earned on the revenue from the acquisitions of BBI and Bio-Stat. The decrease in gross margin percentage for the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007 is driven by the completion of our 50/50 joint venture with P&G in May 2007. As a result of the joint venture, our consumer diagnostic net product sales consist of the manufacturing revenue associated with our manufacturing agreement with the joint venture, whereby we manufacture and sell consumer diagnostic products to the joint venture.

*Vitamins and Nutritional Supplements*

Gross profit from our vitamins and nutritional supplements business decreased by \$0.8 million, or 29%, to \$1.8 million from \$2.6 million, comparing the three months ended September 30, 2008 to the three months ended September 30, 2007. The decrease is primarily the result of shift in product mix to lower margin product sold sales versus the comparative quarter in 2007.

Gross profit from our vitamins and nutritional supplements business increased by \$3.1 million, or 79%, to \$7.0 million from \$3.9 million, comparing the nine months ended September 30, 2008 to the nine months ended September 30, 2007. The increase is primarily the result of improved factory utilization and our cost reduction initiatives in our private label manufacturing business.

As a percentage of net product sales, gross margin for our vitamins and nutritional supplements business was approximately 8% and 11%, for the three and nine months ended September 30, 2008, respectively, compared to 13% and 7%, for the three and nine months ended September 30, 2007, respectively.

**Gross Profit from Services Revenue, Total and by Business Segment.** Gross profit from services revenue was \$71.9 million and \$152.3 million for the three and nine months ended September 30, 2008, respectively, and represents gross profit related to services revenue associated with our newly-formed health management business segment, which includes our recent acquisitions of QAS, Alere, ParadigmHealth and Matria, our professional drugs of abuse testing and screening businesses, and our long-term services agreement related to our consumer diagnostic joint venture formed with P&G in May 2007.

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Professional diagnostic products	\$ 3,611	\$	\$ 11,228	\$
Health management	67,710	1,217	139,167	1,550
Consumer diagnostic products	541	1,090	1,929	1,670
 Total gross profit from services revenue	 \$ 71,862	 \$ 2,307	 \$ 152,324	 \$ 3,220

*Professional Diagnostic Products*

Gross profit from services revenue for our professional diagnostic business segment was \$3.6 million and \$11.2 million for the three and nine months ended September 30, 2008, respectively, and represents gross profit

related to the services provided by our professional drugs of abuse testing and screening business, Redwood, which was acquired in December 2007.

## Table of Contents

As a percentage of our professional diagnostic services revenue, gross margin for the three and nine months ended September 30, 2008 was 49% and 51%, respectively.

### *Health Management*

Gross profit from services revenue for our newly-formed health management business segment was \$67.7 million and \$139.2 million for the three and nine months ended September 30, 2008, respectively, and represents gross profit related to the services provided by our health management businesses, primarily Alere, ParadigmHealth, QAS and Matria.

As a percentage of our health management services revenue, gross margin for the three and nine months ended September 30, 2008 was 57% and 56%, respectively.

### *Consumer Diagnostic Products*

Gross profit from services revenue for our consumer diagnostic business segment was \$0.5 million and \$1.9 million for the three and nine months ended September 30, 2008, respectively, and represents gross profit from services revenue related to our long-term services agreements with the joint venture, pursuant to which we provide certain operational support services to the joint venture. We presently do not allocate any cost of goods sold to the services revenue related to this long-term service agreement. All costs for this segment are recorded in the gross profit from net product sales.

**Research and Development Expense.** Research and development expense increased by \$5.2 million, or 25%, to \$25.7 million for the three months ended September 30, 2008 from \$20.5 million for the three months ended September 30, 2007. The increase in research and development expense for the three months ended September 30, 2008, included approximately \$3.5 million of additional spending related to newly-acquired businesses, primarily Cholestech, HemoSense and the various less significant acquisitions. Research and development expense increased by \$41.8 million, or 94%, to \$86.4 million for the nine months ended September 30, 2008 from \$44.6 million for the nine months ended September 30, 2007. The increase in research and development expense for the nine months ended September 30, 2008, included approximately \$26.6 million of additional spending related to newly-acquired businesses, primarily Biosite, Cholestech, HemoSense and the various less significant acquisitions. Also included in research and development expense was restructuring charges of \$0.3 million and \$6.9 million for the three and nine months ended September 30, 2008, respectively, and \$0.3 million for both the three and nine months ended September 30, 2007. Additionally, our funding arrangement with ITI Scotland Limited was complete as of December 31, 2007 and as such no funding was earned during the three and nine months ended September 30, 2008. This funding arrangement was reflected as an offset to research and development expense in amounts of \$4.8 million and \$13.7 million for the three and nine months ended September 30, 2007, respectively.

Amortization expense of \$1.0 million and \$2.8 million was included in research and development expense for the three and nine months ended September 30, 2008, respectively, and \$0.6 million and \$2.2 million for the three and nine months ended September 30, 2007, respectively.

Research and development expense as a percentage of net revenue was 6% and 7% for the three and nine months ended September 30, 2008, respectively, compared to 9% and 8% for the three and nine months ended September 30, 2007, respectively.

**Purchase of In-Process Research and Development ( IPR&D ).** In connection with of our acquisition of Biosite in 2007, we 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

**Table of Contents**

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 we acquired in connection with the Biosite acquisition (amounts in thousands):

<b>Company/ Year Assets Acquired</b>		<b>Purchase Price</b>		<b>IPR&amp;D (1)</b>		<b>Programs Acquired</b>		<b>Discount Rate Used in Estimating Cash Flows(1)</b>	<b>Year of Expected Launch</b>
Biosite/2007		\$1,800,000		\$ 13,000		Triage Sepsis Panel		15%	2008-2010
				156,000		Triage NGAL		15%	2008-2010
				\$ 169,000					

(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 \$56.1 million, or 116%, to \$104.6 million for the three months ended September 30, 2008, from \$48.5 million for the three months ended September 30, 2007. Sales and marketing expense increased by \$176.5 million, or 168%, to \$281.3 million for the nine months ended September 30, 2008 from \$104.8 million for the nine months ended September 30, 2007. The increase in sales and marketing expense for the three months ended September 30, 2008 relates primarily to additional spending related to newly-acquired businesses. The increase in sales and marketing expense for the nine months ended September 30, 2008 relates primarily to additional spending related to newly-acquired businesses. Also included in sales and marketing expense were restructuring charges of \$0.4 million and \$3.5 million for the three and nine months ended September 30, 2008, respectively, and \$0.1 million and \$0.4 million for the three and nine months ended September 30, 2007, respectively.

Amortization expense of \$41.9 million and \$106.1 million was included in sales and marketing expense for the three and nine months ended September 30, 2008, respectively, and \$11.6 million and \$19.9 million for the three and nine months ended September 30, 2007, respectively.

Sales and marketing expense as a percentage of net revenue increased to 24% and 23% for the three and nine months ended September 30, 2008, respectively, compared to 20% and 19% for both the three and nine months ended September 30, 2007, respectively.

**General and Administrative Expense.** General and administrative expense increased by approximately \$55.9 million, or 195%, to \$84.6 million for the three months ended September 30, 2008, from \$28.7 million for the three months ended September 30, 2007. General and administrative expense increased by approximately \$96.2 million, or 81%, to \$215.4 million for the nine months ended September 30, 2008 from \$119.2 million for the nine months ended September 30, 2007. The increase in general and administrative expense for the three months ended September 30, 2008 relates primarily to additional spending related to newly-acquired businesses. Legal spending increased by approximately \$3.0 million for the three months ended September 30, 2008, as compared to the three months ended September 30, 2007. Also included in general and administrative expense for the three months ended September 30, 2008 is \$3.0 million in restructuring charges representing an increase of approximately \$2.9 million from the comparable period in 2007 and \$4.2 million of stock-based compensation expense, representing an increase of approximately \$2.0 million from the comparable period in 2007. The increase in general and administrative expense for the nine months ended September 30, 2008 relates primarily to additional spending related to newly-acquired businesses. Legal spending increased by approximately \$9.9 million for the nine months ended September 30, 2008, as compared to the nine months ended September 30, 2007. Also included in general and administrative expense for the nine months ended September 30, 2008 is \$6.1 million in restructuring charges representing an increase of approximately \$5.3 million

**Table of Contents**

from the comparable period in 2007 and \$12.0 million of stock-based compensation expense, representing a decrease of approximately \$37.5 million from the comparable period in 2007 which included a charge of \$45.2 million related to our acquisition of Biosite.

Amortization expense of \$6.4 million and \$11.3 million was included in general and administrative expense for the three and nine months ended September 30, 2008, respectively, and \$0.1 million and \$0.2 million for the three and nine months ended September 30, 2007, respectively.

General and administrative expense as a percentage of net revenue increased to 19% for the three months ended September 30, 2008, as compared to 12% for the three months ended September 30, 2007, and decreased to 18% for the nine months ended September 30, 2008 as compared to 22% for the nine months ended September 30, 2007.

**Interest Expense.** Interest expense includes interest charges, the write-off and amortization of deferred financing costs and the amortization of non-cash discounts associated with our debt issuances. Interest expense decreased by \$5.4 million, or 19%, to \$23.6 million for the three months ended September 30, 2008, from \$29.0 million for the three months ended September 30, 2007. Interest expense increased by \$22.5 million, or 40%, to \$78.8 million for the nine months ended September 30, 2008, from \$56.2 million for the nine months ended September 30, 2007. The decrease in interest expense for the three months ended September 30, 2008 primarily relates to lower interest rates on outstanding debt versus the comparable period in 2007. The increase in interest expense for the nine months ended September 30, 2008 was partially due to \$6.6 million in interest expense related to the accelerated present value accretion of our lease restoration costs due to the early termination of our facility lease in Bedford, England recorded in connection with our 2008 restructuring plans. Contributing to the increase for the nine months ended September 30, 2008 was \$0.8 million of interest expense recorded in connection with a legal settlement with one of our distributors in June 2008. Additionally, such increase was a result of higher average outstanding debt balances during the nine months ended September 30, 2008, compared to the nine months ended September 30, 2007. 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.

**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):

	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2008</b>	<b>2007</b>	<b>Change</b>	<b>2008</b>	<b>2007</b>	<b>Change</b>
Interest income	\$ 472	\$ 1,412	\$ (940)	\$ 5,606	\$ 7,678	\$ (2,072)
Foreign exchange gains (losses), net	(3,056)	1,290	(4,346)	(4,907)	2,615	(7,522)
Other	1,432	(559)	1,991	(6,088)	(1,471)	(4,617)
Total other income (expense), net	\$ (1,152)	\$ 2,143	\$ (3,295)	\$ (5,389)	\$ 8,822	\$ (14,211)

Interest income of \$0.5 million and \$5.6 million for the three and nine months ended September 30, 2008, respectively decreased by \$0.9 million and \$2.1 million, compared to the three and nine months ended September 30, 2007, respectively. This decrease is primarily the result of less interest earned on lower cash balances.

Other income of \$1.4 million for the three months ended September 30, 2008 includes \$0.3 million of income associated with a favorable settlement of a prior year's royalty collected during the quarter. Other expense of \$6.1 million for the nine months ended September 30, 2008 includes a \$12.5 million charge associated with an arbitration decision, partially offset by \$5.6 million of income associated with a favorable settlement of a prior year's royalty collected during the nine-month period. 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.

**(Benefit) Provision for Income Taxes.** The benefit for income taxes increased by \$3.1 million, to a \$4.7 million benefit for the three months ended September 30, 2008, from a \$1.6 million benefit for the three months ended

**Table of Contents**

September 30, 2007. The provision for income taxes decreased by \$14.8 million, to a \$13.3 million benefit for the nine months ended September 30, 2008, from a \$1.6 million provision for the nine months ended September 30, 2007. The effective tax rate was 40.3% and 25.6% for the three and nine months ended September 30, 2008, compared to 0.9% and (0.7)% for the three and nine months ended September 30, 2007. The income tax benefit for the nine months ended September 30, 2008 is primarily related to the recognition of the federal income tax benefit and foreign income tax benefits for various foreign subsidiaries. The income tax benefit for the three months ended September 30, 2008 is primarily related to the recognition of the federal income tax benefit and foreign income tax benefits for various foreign subsidiaries. The income tax benefit for the three months ended September 30, 2007 includes 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 (Losses) in Unconsolidated Entities, Net of Tax.** Equity earnings (losses) 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 (losses) in unconsolidated entities, net of tax, for the three and nine months ended September 30, 2008 reflects the following: (i) earnings (losses) from our 50% interest in our joint venture with P&G in the amount of \$2.8 million and \$(0.2) million, respectively, (ii) earnings from our 40% interest in Vedalab S.A., or Vedalab, in the amount of \$0.1 million and \$0.2 million, respectively, and (iii) earnings from our 49% interest in TechLab, Inc., or TechLab, in the amount of \$0.3 million and \$1.2 million, respectively. Included in our earnings (losses) from our 50% joint venture with P&G for the nine months ended September 30, 2008 are restructuring charges associated with the announced closure of our Unipath facility located in Bedford, England in the amount of \$6.0 million, which represents our 50% share of a total \$11.2 million of restructuring charges borne by the joint venture. Of the \$11.2 million, \$7.4 million related to fixed asset impairments, \$3.6 million related to early termination lease penalties and \$0.2 million related to severance costs.

**Net Loss.** We incurred a net loss of \$3.7 million, or \$0.12 per basic and diluted common share, for the three months ended September 30, 2008, compared to net loss of \$180.6 million, or \$3.74 per basic and diluted common share, for the three months ended September 30, 2007. We incurred a net loss of \$38.2 million, or \$0.60 per basic and diluted common share, for the nine months ended September 30, 2008, compared to net loss of \$229.0 million, or \$4.89 per basic and diluted common share, for the nine months ended September 30, 2007. The net loss for the three and nine months ended September 30, 2008, compared to the net loss for the three and nine months ended September 30, 2007, primarily resulted from the various factors as discussed above. See Note 5 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 currently expect to fund our short and long-term working capital needs and other commitments primarily through our operating cash flow, and we expect our working capital position to improve as we improve our operating margins and grow our business through new product introductions and by continuing to leverage our strong intellectual property position. At this point in time, our liquidity has not been materially impacted by the recent and unprecedented disruption in the current capital and credit markets and we do not expect that it will be materially impacted in the near future. We will continue to closely monitor our liquidity and the capital and credit markets. However, we cannot predict with any certainty the impact to us of any further disruption in the credit environment.

In addition, we may also utilize our revolving credit facility, or other sources of financing, to fund a portion of our capital needs and other future commitments, including future acquisitions. If the capital and credit markets continue to experience volatility and the availability of funds remains limited, we may incur increased costs associated with issuing commercial paper and/or other debt instruments. In addition, it is possible that our ability to access the capital and credit markets may be limited by these or other factors at a time when we would like, or need, to do so, which could have an impact on our ability to refinance maturing debt and/or react to changing economic and business conditions.

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

41

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## **Table of Contents**

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.

As of September 30, 2008, in addition to other indebtedness, we had approximately \$1.1 billion in aggregate principal amount of indebtedness outstanding under our First Lien Credit Agreement, \$250.0 million in aggregate principal amount of indebtedness outstanding under our Second Lien Credit Agreement (collectively with the First Lien Credit Agreement, the secured credit facilities), and \$150.0 million in indebtedness under our outstanding 3% senior subordinated convertible notes, or the senior subordinated convertible notes. Included in the secured credit facilities is a revolving line-of-credit of \$150.0 million, of which \$142.0 million was outstanding as of September 30, 2008.

Interest on our First Lien indebtedness, 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 Revolving Loans that are Base Rate Loans, each as in effect from time to time. The Base Rate is a floating rate which approximates the U.S. Prime rate and changes on a periodic basis. The Eurodollar Rate is equal to the LIBOR rate and is set for a period of one to three months at our election. 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%.

The outstanding indebtedness under the Second Lien Credit Agreement is a term loan in the amount of \$250.0 million. 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%.

For the three and nine months ended September 30, 2008, interest expense, including amortization of deferred financing costs, under the secured credit facilities was \$21.3 million and \$64.9 million, respectively. For the three and nine months ended September 30, 2007, we recorded interest expense, including amortization of deferred financing costs, under our previous senior credit facility in the aggregate amount of \$1.2 million and \$3.7 million, respectively. Included in interest expense for the three and nine months ended September 30, 2007, is the write-off of \$0 and \$2.6 million, respectively, in unamortized deferred financing costs. As of September 30, 2008, accrued interest related to the secured credit facilities amounted to \$1.7 million. As of September 30, 2008, we were in compliance with all debt covenants related to the above debt, which consisted principally of maximum consolidated leverage and minimum interest coverage requirements.

Interest expense related to our senior subordinated convertible notes for the three and nine months ended September 30, 2008, including amortization of deferred financing costs, was \$1.2 million and \$3.7 million, respectively. As of September 30, 2008, accrued interest related to the senior subordinated convertible notes amounted to \$1.7 million.

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 pay us variable interest at the three-month LIBOR rate, and we pay the counterparties a fixed rate of

42

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## **Table of Contents**

4.85%. These interest rate swap contracts were entered into to convert \$350.0 million of the \$1.2 billion variable rate term loan under the secured credit facility into fixed rate debt.

As of September 30, 2008, we had 1.8 million shares of our Series B preferred stock issued and outstanding. Upon a conversion of these shares of Series B preferred stock, we may, at our option and in our sole discretion, satisfy the entire conversion obligation in cash, or through a combination of cash and common stock, to the extent permitted under our secured credit facilities and under Delaware law.

### *Summary of Changes in Cash Position*

As of September 30, 2008, we had cash and cash equivalents of \$154.2 million, a \$260.6 million decrease from December 31, 2007. Our primary sources of cash during the nine months ended September 30, 2008, included \$114.3 million generated by our operating activities, \$18.6 million from common stock issues under employee stock option and stock purchase plans, \$138.3 million from borrowing under of existing credit facilities, and a decrease of \$138.2 million in restricted cash. Investing activities during the nine months ended September 30, 2008 used a total of \$657.7 million of cash, net of cash acquired, primarily related to our acquisition activities and capital expenditures. Our financing activities, aside from the decrease in restricted cash, proceeds from borrowings under our secured credit facilities and cash received from common stock issues under employee stock option and stock purchase plans, used \$11.6 million of cash related to repayments under our secured credit facilities and capital lease obligations. Fluctuations in foreign currencies positively impacted our cash balance by \$0.3 million during the nine months ended September 30, 2008.

### *Cash Flows from Operating Activities*

Net cash provided by operating activities during the nine months ended September 30, 2008 was \$114.3 million, which resulted from \$215.6 million of non-cash items, offset by our net loss of \$38.2 million and \$63.1 million of cash used to meet net working capital requirements during the period. The \$215.6 million of non-cash items included \$194.2 million related to depreciation and amortization, \$22.6 million related to the impairment of assets, \$19.7 million related to non-cash stock-based compensation expense and \$4.4 million related to the amortization of deferred financing costs, partially offset by a \$28.3 million decrease related to the recognition of a tax benefit for current year losses and a \$1.2 million decrease related to equity investments in unconsolidated entities.

### *Cash Flows from Investing Activities*

Our investing activities during the nine months ended September 30, 2008 utilized \$657.7 million of cash, including \$614.2 million used for acquisitions and transaction-related costs, net of cash acquired, \$46.8 million of capital expenditures, net of proceeds from sale of equipment, partially offset by a \$3.2 million decrease in investments and other assets, which included an \$11.2 million return of cash from our 50/50 joint venture with P&G.

Significant acquisitions during the nine months ended September 30, 2008 included Matria, BBI and Panbio, which accounted for approximately \$561.5 million of the \$614.2 million of cash used for acquisitions.

### *Cash Flows from Financing Activities*

Net cash provided by financing activities during the nine months ended September 30, 2008 was \$282.5 million. During 2007, in connection with the pending acquisition of BBI, a restricted cash balance was created in the amount of approximately \$140.5 million. Subsequent to the acquisition of BBI in February 2008, this cash balance became unrestricted and available for future financing-related activities. Additionally, financing activities provided \$18.6 million from issuance of common stock under employee stock option and stock purchase plans, as well as \$138.3 million from borrowings under existing credit facilities.

As of September 30, 2008, we had an aggregate of \$1.4 million in outstanding capital lease obligations which are payable through 2012.

**Table of Contents***Income Taxes*

As of December 31, 2007, we had approximately \$330.3 million of domestic net operating loss ( NOL ) carryforwards and \$31.2 million of foreign NOL carryforwards, respectively, which either expire on various dates through 2027 or can be carried forward indefinitely. These losses are available to reduce federal and foreign taxable income, if any, in future years. These losses are also subject to review and possible adjustments by the applicable taxing authorities. In addition, the domestic operating loss carryforward amount at December 31, 2007 included approximately \$205.6 million of pre-acquisition losses at Alere, ParadigmHealth, Biosite, Cholestech, Diamics, Inc., or Diamics, HemoSense, Inverness Medical Nutritionals Group, or IMN, Ischemia, Inc., or Ischemia, Ostex International, Inc., or Ostex, and Advantage Diagnostics Corporation, or ADC. The foreign operating loss carryforward amount included approximately \$12.7 million of pre-acquisition losses at CLONDIAG chip technologies GmbH, or Clondia. The future benefit of both the domestic and foreign 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 carryforwards at December 31, 2007 was approximately \$10.2 million resulting from the exercise of employee stock options, the tax benefit of which, when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax.

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

**Off-Balance Sheet Arrangements**

We had no material off-balance sheet arrangements as of September 30, 2008.

**Contractual Obligations**

The following table summarizes our principal contractual obligations as of September 30, 2008 that have changed significantly since December 31, 2007 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, as amended, for the year ended December 31, 2007 but omitted in the table below represent those that have not changed significantly since that date (in thousands):

<b>Contractual Obligations</b>	<b>Total</b>	<b>Payments Due by Period</b>			
		<b>2008</b>	<b>2009-2010</b>	<b>2011-2012</b>	<b>Thereafter</b>
Long-term debt obligations (1)	\$ 1,524,147	\$ 8,391	\$ 29,638	\$ 22,197	\$ 1,463,921
Operating lease obligations	134,720	23,497	38,553	25,265	47,405
Purchase obligations capital expenditures	16,874				16,874
Purchase obligations other	64,137	62,065	2,072		
	\$ 1,739,878	\$ 93,953	\$ 70,263	\$ 47,462	\$ 1,528,200

(1) Long-term debt obligations increased by \$144.0 million since December 31, 2007, primarily

due to the  
utilization of  
\$142.0 million  
on our revolving  
line-of-credit for  
the acquisition  
of Matria in  
May 2008.

As of September 30, 2008, we have contingent consideration contractual terms related to our acquisitions of Alere, Binax, Inc., or Binax, Bio-Stat, Clondiag, Diamics, First Check, Gabmed, Matritech, Promesan, Spectral/Source, our most recently acquired healthcare business, Vision Biotech Pty Ltd., or Vision, and Global Diagnostic CC, or Global. With the exception of Alere, the contingent considerations will be accounted for as increases in the aggregate purchase prices if and when the contingencies occur.



**Table of Contents**

With respect to Alere, the terms of the acquisition agreement provided for contingent consideration payable to each Alere stockholder who owned shares of our common stock or retained the option to purchase shares of our common stock on the 6-month anniversary of the closing of the acquisition. The contingent consideration, payable in cash or stock at our election, was equal to the number of such shares of our common stock or options to purchase our common stock held on the 6-month anniversary multiplied by the amount that \$58.31 exceeded the greater of the average price of our common stock for the 10 business days preceding the 6-month anniversary date, or 75% of \$58.31.

Accordingly, based on the price of our common stock for the 10 business days preceding the 6-month anniversary of the closing of the acquisition, we issued approximately 0.1 million shares of our common stock on May 30, 2008 to the Alere stockholders based on the remaining outstanding shares at that time. Payment of this contingent consideration did not impact the purchase price for this acquisition.

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. As of September 30, 2008, the remaining contingent consideration to be earned is approximately \$7.3 million.

With respect to Bio-Stat, the terms of the acquisition provide for contingent consideration payable in the form of loan notes to the Bio-Stat shareholders, if certain EBITDA (earnings before interest, taxes, depreciation and amortization) milestones are met for 2007. The EBITDA milestones were met in 2007 and loan notes totaling \$6.2 million were issued during the third quarter of 2008 and remain outstanding as of September 30, 2008.

With respect to Clondia, the terms of the acquisition agreement provide for \$8.9 million of contingent consideration, consisting of approximately 0.2 million shares of our common stock and approximately \$3.0 million of cash or stock in the event that four specified products are developed on Clondia's platform technology during the three years following the acquisition date. Successful completion of the second milestone occurred during the first quarter of 2008 for which we made a payment for \$0.9 million and issued 56,080 shares of our common stock during the first quarter of 2008. Successful completion of the third and fourth milestones occurred during the third quarter of 2008 and, accordingly, accrued contingent consideration of \$4.8 million was accrued as of September 30, 2008.

With respect to Diamics, the terms of the acquisition agreement provide for contingent consideration payable upon the successful completion of certain milestones, including development of business plans and marketable products. As of September 30, 2008, the remaining contingent consideration to be earned is approximately \$2.3 million.

With respect to First Check, the terms of the acquisition agreement require us to 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. The 2007 milestone, totaling \$2.2 million, was met and accrued as of December 31, 2007 and was paid during the first quarter of 2008. As of September 30, 2008, the second earn-out requirements were met resulting in accrued contingent consideration of \$0.3 million during the third quarter of 2008.

With respect to Gabmed, the terms of the acquisition agreement provide for contingent consideration totaling up to 750,000 payable in up to five annual amounts beginning in 2007, upon successfully meeting certain revenue and EBIT (earnings before interest and taxes) milestones in each of the respective annual periods. The 2007 milestone, totaling 0.1 million (\$0.2 million), was met and accrued as of June 30, 2008, and was paid during the third quarter of 2008.

With respect to Matritech, the terms of the acquisition agreement require us to pay an earn-out to the former Matritech shareholders upon successfully meeting certain revenue targets in 2008. As of September 30, 2008, no milestones have been met.

With respect to Promesan, the terms of the acquisition agreement provide for contingent consideration payable upon successfully meeting certain annual revenue targets. Total contingent consideration of up to 0.6 million is payable in three equal annual amounts of 0.2 million beginning in 2007 and ending in 2009. The 2007 milestone,

## **Table of Contents**

totaling 0.2 million (\$0.3 million), was met and accrued as of December 31, 2007 and was paid during the first quarter of 2008.

With respect to Spectral/Source, the terms of the acquisition agreement require us to 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. As of September 30, 2008, revenue and profit milestones were achieved resulting in accrued contingent consideration of \$2.7 million.

With respect to our most recently acquired healthcare business, the terms of the acquisition agreement provide for contingent consideration payable upon successfully meeting certain revenue and EBITDA targets for the twelve months ending June 30, 2009 and December 31, 2010, respectively. As of September 30, 2008, we accrued a liability in the amount of \$5.8 million to avoid recognition of negative goodwill, as a result of not recognizing additional purchase price consideration that is contingent on future events.

With respect to Vision, the terms of the acquisition agreement provide for incremental consideration payable to the former Vision shareholders. The maximum amount of incremental consideration payable is approximately \$3.2 million, of which \$1.0 million is guaranteed and accrued as of September 30, 2008. The remaining contingent consideration is payable upon the completion of certain milestones and successfully maintaining certain production levels and product costs during each of the two years following the acquisition date.

With respect to Global, the terms of the acquisition agreement provide for contingent consideration payable upon successfully meeting certain revenue targets in 2008. As of September 30, 2008, no milestones have been met.

### **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, 2007 included in our Annual Report on Form 10-K, as amended, include a comprehensive summary of the significant accounting policies and methods used in the preparation of our consolidated financial statements.

#### *Revenue Recognition*

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

The majority of our revenue is derived from product revenue. 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.

Additionally, we generate services revenue in connection with contracts with leading healthcare organizations whereby we distribute clinical expertise through fee-based arrangements. Revenue for fee-based arrangements is recognized over the period in which the services are provided. Some contracts provide that a portion of our fees are

**Table of Contents**

at risk if our customers do not achieve certain financial cost savings over a period of time, typically one year. Revenue subject to refund is not recognized if (i) sufficient information is not available to calculate performance measurements, or (ii) interim performance measurements indicate that we are not meeting performance targets. If either of these two conditions exists, we record the amounts as other current liabilities in the consolidated balance sheet, deferring recognition of the revenue until we establish that we have met the performance criteria. If we do not meet the performance targets at the end of the contractual period we are obligated under the contract to refund some or all of the at risk fees.

In connection with the acquisition of the Determine business in June 2005 from Abbott Laboratories, we entered into a transition services agreement with Abbott, whereby Abbott would continue to distribute the acquired products until both parties agreed the transition was completed. 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, we record 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 \$10.9 million and \$33.4 million, or 4% of net product sales for both the three and nine months ended September 30, 2008, respectively, compared to \$12.3 million and \$39.4 million, or 5% and 7%, respectively, of net product sales for the three and nine months ended September 30, 2007, respectively, which have been recorded against product sales to derive our net product sales.

Similarly, our management must make estimates regarding uncollectible accounts receivable balances. When evaluating the adequacy of the allowance for doubtful accounts, management analyzes specific accounts receivable balances, historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in our customer payment terms and patterns. Our accounts receivable balance was \$268.4 million and \$163.4 million, net of allowances for doubtful accounts of \$9.2 million and \$12.2 million, as of September 30, 2008 and December 31, 2007, respectively.

*Valuation of Inventories*

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



## **Table of Contents**

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 \$196.6 million and \$148.2 million, net of a provision for excess and obsolete inventory of \$10.3 million and \$8.1 million, as of September 30, 2008 and December 31, 2007, 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, 2008, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, was \$287.3 million, \$3.1 billion and \$1.7 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 professional diagnostic, health management and consumer diagnostic reporting segments, which amounted to \$1.7 billion, \$1.3 billion and \$51.4 million, respectively, as of September 30, 2008. Goodwill as of December 31, 2007, related to our newly-formed health management business segment in the amount of \$463.1 million has been reclassified from Professional Diagnostic Products to Health Management as of December 31, 2007. As of September 30, 2007, 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 reporting units was 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, 2007, 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, 2007, that would require us to reassess whether the carrying values of our goodwill have been impaired.



## **Table of Contents**

### **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, 2008, 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. The expected term is based on the assumption that all outstanding options will exercise at the midpoint of the vesting date and the full contractual term, including data on experience to date. As stock-based compensation expense is recognized in our consolidated statement of operations is based on awards ultimately expected to vest, the amount of expense has been reduced for estimated forfeitures. SFAS No. 123-R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. If factors change and we employ different assumptions in the application of SFAS No.123-R, the compensation expense that we record in future periods may differ significantly from what we have recorded in the current period.

### **Accounting for Income Taxes**

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

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a valuation allowance of \$18.9 million as of December 31, 2007 due to uncertainties related to the future benefits, if any, from our deferred tax assets related primarily to our U.S. businesses and certain foreign net operating losses and tax credits. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to establish an additional valuation allowance or reduce our current valuation allowance which could materially impact our tax provision.

On January 1, 2007 we adopted Financial Accounting Standards Board ( FASB ) Interpretation No. 48 ( FIN 48 ), *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement 109*. In accordance with FIN 48, we established reserves for tax uncertainties that reflect the use of the comprehensive model for the recognition and measurement of uncertain tax positions. We are currently undergoing routine tax examinations by various state and foreign jurisdictions. Tax authorities periodically challenge certain transactions and deductions we





## **Table of Contents**

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.

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, as amended, for the year ended December 31, 2007, titled Item 3. Legal Proceedings, and in Part II, Item 1, Legal Proceedings of this Quarterly Report on Form 10-Q 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, 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.

On September 19, 2008, the Estate of Melissa Prince Quisenberry filed a class action complaint in the Superior Court of California on behalf of herself and others similarly situated against Alere and Agora Parent, Inc., both our wholly owned subsidiaries; Ronald D. Geraty, MD, Chief Executive Officer of Alere and certain other individuals who were executive officers, directors and/or significant shareholders of Alere (collectively the Alere Individual Defendants); as well as certain other unaffiliated entities alleging that the Alere Individual Defendants breached fiduciary duties of good faith, fair dealing, loyalty and candor; and that Alere and certain unaffiliated entities aided, abetted and substantially participated in the breach of fiduciary duty. Plaintiff and class owned common and/or preferred stock in Alere and allege that the defendants forced them to tender their stock in connection with the March 14, 2007 sale of Alere to an unaffiliated entity at a price which was substantially lower than the price at which we bought Alere on October 24, 2007.

Otherwise, we are not a party to any legal proceedings that we currently believe could materially adversely affect our results of operations or financial condition or net cash flows.

## **Recent Accounting Pronouncements**

### *Recently Issued Standards*

In October 2008, the FASB issued FASB Staff Position ( FSP ) 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*. FSP 157-3 clarifies the application of SFAS No. 157 in an inactive market. It demonstrated how the fair value of a financial asset is determined when the market for that financial asset is inactive. FSP 157-3 was effective upon issuance, including prior periods for which financial statements had not been issued. The adoption of these provisions did not have a material impact on our consolidated financial statements.

In June 2008, the FASB ratified EITF Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock*, which addresses the accounting for certain instruments as derivatives under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. Under this new pronouncement, specific guidance is provided regarding requirements for an entity to consider embedded features as

## **Table of Contents**

indexed to the entity's own stock. This Issue is effective for fiscal years beginning after December 15, 2008. We are currently in the process of evaluating the impact of adopting this pronouncement.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. This statement identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the United States. This statement is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. We do not expect SFAS No. 162 to have a material impact on our consolidated financial statements.

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled In Cash upon Conversion (Including Partial Cash Settlement)*. FSP APB 14-1 specifies that issuers of such instruments should separately account for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. FSP APB 14-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. We are currently in the process of evaluating the impact of adopting this pronouncement.

In April 2008, the FASB issued FSP 142-3, *Determination of the Useful Life of Intangible Assets*. FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, as well as interim periods within those fiscal years. We are currently in the process of evaluating the impact of adopting this pronouncement.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities – an Amendment of FASB Statement No. 133*. This statement requires entities that utilize derivative instruments to provide qualitative disclosures about their objectives and strategies for using such instruments, as well as any details of credit-risk-related contingent features contained within derivatives. It also requires entities to disclose additional information about the amounts and location of derivatives located within the financial statements, how the provisions of SFAS No. 133 have been applied and the impact that hedges have on an entity's financial position, financial performance and cash flows. This statement is effective for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. We are currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB ratified the consensus reached by the EITF in EITF Issue No. 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*. The EITF concluded that a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. Revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, and other accounting literature. Payments to or from collaborators would be evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature. The nature and purpose of collaborative arrangements are to be disclosed along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF Issue No. 07-01 applies to the entire collaborative agreement. This Issue is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We are currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an Amendment of Accounting Research Bulletin (ARB) No. 51*. This statement amends ARB No. 51 to establish accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a non-controlling interest in a subsidiary is an ownership interest in the consolidated entity and should therefore be reported as equity in the consolidated financial statements. The



## **Table of Contents**

statement also establishes standards for presentation and disclosure of the non-controlling results on the consolidated income statement. SFAS No. 160 is effective for fiscal years beginning on or after December 15, 2008. We are currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB issued SFAS No. 141-R, *Business Combinations*. This statement replaces SFAS No. 141, but retains the fundamental requirements in SFAS No. 141 that the acquisition method of accounting be used for all business combinations. This statement requires an acquirer to recognize and measure the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at their fair values as of the acquisition date. The statement requires acquisition costs and any restructuring costs associated with the business combination to be recognized separately from the fair value of the business combination. SFAS No. 141-R establishes requirements for recognizing and measuring goodwill acquired in the business combination or a gain from a bargain purchase as well as disclosure requirements designed to enable users to better interpret the results of the business combination. SFAS No. 141-R is effective for fiscal years beginning on or after December 15, 2008. Given our history of acquisition activity, we anticipate the adoption of SFAS No. 141-R to have a significant impact on our consolidated financial statements. Early adoption of this statement is not permitted.

### *Recently Adopted Standards*

Effective January 1, 2008, we adopted 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. The effect of applying this EITF is prospective for new contracts entered into on or after the date of adoption. The adoption of this EITF did not have a material impact on our consolidated financial statements.

Effective January 1, 2008, we adopted 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. The adoption of these provisions did not have a material impact on our consolidated financial statements.

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, for financial assets and liabilities, as well as for any other assets and liabilities that are carried at fair value on a recurring basis in financial statements. The FASB has provided a one year deferral for the implementation for other non-financial assets and liabilities. Earlier application is encouraged. We adopted the required provisions of SFAS No. 157 on January 1, 2008. The adoption of these provisions did not have a material impact on our consolidated financial statements. For further information about the adoption of the required provisions of SFAS No. 157 see Note 13.

### **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



**Table of Contents**

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, as amended, for the fiscal year ending December 31, 2007 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;

the impact of poor economic conditions and financial markets, including the current credit markets, on our plans and operations and those of our suppliers and customers;

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;

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

the impact of business combinations, including acquisitions and divestitures;

our ability to establish a 50/50 joint venture, or an alternative arrangement offering similar economic benefits, for our health management business and to successfully put to use the proceeds we expect to receive in connection with any such joint venture or other arrangement;

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

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

## **Table of Contents**

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, 2008, our short-term investments approximated market value.

At September 30, 2008, we had a term loan in the amount of \$963.2 million and a revolving line-of-credit available to us of up to \$150.0 million, of which \$142.0 million was outstanding as of September 30, 2008, 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 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. The Base Rate is a floating rate which approximates the U.S. Prime rate and changes on a periodic basis. The Eurodollar Rate is equal to the LIBOR rate and is set for a period of one to three months at our election. 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, 2008, 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 \$1.2 billion variable rate term loan under the senior credit facility into fixed rate debt.

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, 2008 over the next twelve months is quantified and summarized as follows (in thousands):



**Table of Contents****Interest Expense  
Increase**

Interest rates increase by 100 basis points	\$ 8,632
Interest rates increase by 200 basis points	\$ 17,264

**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, 2008, the net impact of foreign currency changes on transactions was a loss of \$3.1 million and \$4.9 million, respectively. Generally, we do not use derivative financial instruments or other financial instruments with original maturities in excess of three months to hedge such economic exposures.

Gross margins of products we manufacture at our European plants and sell in U.S. Dollar are also affected by foreign currency exchange rate movements. Our gross margin on total net product sales was 49.8% for the three months ended September 30, 2008. 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, 2008, our gross margin on total net product sales would have been 49.9%, 50.1% and 50.3%, respectively. Our gross margin on total net product sales was 48.8% for the nine months ended September 30, 2008. 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, 2008, our gross margin on total net product sales would have been 48.9%, 49.1% and 49.3%, 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 uniformly stronger by 1%, 5% or 10%, compared to the actual average exchange rates used to translate the financial results of each of our foreign subsidiaries, our net product sales revenue and our net loss would have been impacted by approximately the following amounts (in thousands):

**If, during the three months  
ended September 30, 2008, the  
U.S. dollar was stronger by:**

	<b>Approximate decrease in net revenue</b>	<b>Approximate increase in net loss</b>
1%	\$ 962	\$ 18
5%	\$ 4,811	\$ 88
10%	\$ 9,621	\$ 177

**If, during the nine months  
ended September 30, 2008, the  
U.S. dollar was stronger by:**

	<b>Approximate decrease in net revenue</b>	<b>Approximate decrease in net loss</b>
1%	\$ 2,621	\$ 46
5%	\$ 14,029	\$ 228
10%	\$ 28,289	\$ 455

**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 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 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

55

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## Table of Contents

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 1. LEGAL PROCEEDINGS**

On September 19, 2008, the Estate of Melissa Prince Quisenberry filed a class action complaint in the Superior Court of California on behalf of herself and others similarly situated against Alere Medical Inc. ( Alere ) and Agora Parent, Inc., both our wholly owned subsidiaries; Ronald D. Geraty, MD, Chief Executive Officer of Alere and certain other individuals who were executive officers, directors and/or significant shareholders of Alere (collectively the Alere Individual Defendants ); as well as certain other unaffiliated entities alleging that the Alere Individual Defendants breached fiduciary duties of good faith, fair dealing, loyalty and candor; and that Alere and certain unaffiliated entities aided, abetted and substantially participated in the breach of fiduciary duty. Plaintiff and class owned common and/or preferred stock in Alere and allege that the defendants forced them to tender their stock in connection with the March 14, 2007 sale of Alere to an unaffiliated entity at a price which was substantially lower than the price at which we bought Alere on October 24, 2007.

Otherwise we are not a party to any pending legal proceedings that we currently believe could materially adversely affect our results of operations or financial condition or net cash flows. However, as discussed in our Annual Report on Form 10-K, as amended, for fiscal 2007, we are subject at any particular time to various types of lawsuits arising in the ordinary course of our business. These suits often involve employment or commercial matters, including claims of patent infringement. Our subsidiary Alere Medical, Inc. is currently defending infringement claims brought by Health Hero Network, Inc. ( Health Hero ), which alleges to have patented certain processes related to home monitoring of patients. While we believe that we have strong defenses to Health Hero s claims and intend to defend the claims vigorously, these, or other infringement claims, could potentially impact existing or future business opportunities. The United States Patent and Trademark Office has already granted our requests for reexamination of several of the Health Hero patents in suit. On November 4, 2008, we were made aware of infringement claims brought by Healthways, Inc. and Robert Bosch North America, Inc., owner of Health Hero, under different patents. This action has not been formally served on us. We have not been able to fully assess these new claims. We intend to vigorously defend these claims and consider filing counterclaims in response.

We are also subject to claims brought by investors. See Part II, Item 1, Legal Proceedings, of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2008 for a description of a purported federal securities class action lawsuit against us and certain of our executive officers.

### **ITEM 1A. RISK FACTORS**

There have been no material changes from the Risk Factors previously disclosed in Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K, as amended, for the fiscal year ending December 31, 2007, except for the following:

**Disruptions in the capital and credit markets related to the current national and world-wide financial crisis, which may continue indefinitely or intensify, could adversely affect our results of operations, cash flows and financial condition, or those of our customers and suppliers.**

The current disruptions in the capital and credit markets may continue indefinitely or intensify, and adversely impact our results of operations, cash flows and financial condition, or those of our customers and suppliers. These disruptions could adversely affect our ability to draw on our bank revolving credit facility, which is dependent on the ability of the banks that are parties to the facility to meet their funding commitments. Those banks may not be able to meet their funding commitments to us if they experience shortages of capital and liquidity. Disruptions in the capital and credit markets as a result of uncertainty, changing or increased regulation, reduced alternatives or failures of significant financial institutions could adversely affect our access to liquidity needed to conduct or



**Table of Contents**

expand our businesses or conduct acquisitions or make other discretionary investments, as well as our ability to effectively hedge our currency or interest rate. Such disruptions may also adversely impact the capital needs of our customers and suppliers, which, in turn, could adversely affect our results of operations, cash flows and financial condition.

**ITEM 6. EXHIBITS**

**Exhibits:**

Exhibit No. Description

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 6, 2008

/s/ DAVID TEITEL

David Teitel  
Chief Financial Officer and an authorized  
officer